Secretary Burwell's Hearing on
"The President's Fiscal Year 2017 Budget"
Ways & Means Committee
February 10, 2016

All responses are accurate as of February 10, 2016

Questions for the Record: Secretary Burwell

Questions from Representative Tiberi of Ohio:

Secretary Burwell, as you well know, Obamacare's CO-OP program has been a disaster. After using the American taxpayer as a piggybank, more than half of these entities have failed. I know many of my colleagues share my concerns, and I want to highlight a recent incident with a CO-OP in Ohio, InHealth. Press reports have indicated that InHealth is under enhanced oversight, which means CMS is concerned about its financial stability and is closely monitoring its operations. About 9,000 Ohioans are enrolled in InHealth, and they recently got some surprising news: at the last minute, InHealth decided to drop most OhioHealth hospitals and doctors from their provider network leaving them with few options now that open enrollment has passed. Now, I understand that this Obamacare CO-OP is struggling— that's what happens when Washington thinks it knows best and engages in crony capitalism. And I understand that they are just one of many issuers forced to narrow provider networks because of Obamacare's mandates and regulations.

But what I don't understand is how an Administration that crows about consumer and patient protections in the President's health care law can allow a CO-OP it is so closely monitoring to pull the wool over people's eyes and not announce major changes to provider networks until after the open enrollment period has passed.

1. **Secretary Burwell, is monitoring decisions about providers networks part of CMS's enhanced oversight of the CO-OPs? Will there be recourse for enrollees who feel tricked?**

Answer: We are focused on monitoring and supporting the remaining CO-OPs and making sure that consumers whose CO-OPs will not offer coverage for 2016 retain access to high-quality, affordable health insurance.

There are inherent risks in any start up; the insurance market is especially challenging. Each CO-OP is different and faces its own unique challenges. CO-OPs entered the health insurance market with a number of challenges, including: building a provider network

and no previous claims experience on which to base pricing, while facing competition from larger, experienced issuers.

Provider networks are established via private contracts between health care providers and insurers, including CO-OPs, who frequently negotiate about the terms of such agreements, and frequently change from year to year. We continue to monitor network adequacy to determine whether networks meet requirements, and will work with state departments of insurance to resolve consumer complaints.

While I understand the disruption a decision like this can cause for consumers, it is important to note that plans still must maintain adequate networks that meet federal and state standards. If consumers are concerned that their plans aren't meeting these standards, they should contact their state Department of Insurance, which has primary authority for overseeing network adequacy.

2. **Secretary Burwell, I was intrigued by the statement in the budget that the Administration believes it has increased the solvency of the Hospital Trust Fund by 15 years.**

   Can you provide the Committee with a detailed breakdown of the policies that yield enough savings to gain 15 years?

Answer: The proposed changes in health and tax policies included in the FY 2017 budget would help extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years. These changes are outlined in the second response below.

3. **Specifically, can you highlight the Medicare Part A savings and the increased taxes the Administration has identified to achieve this outcome?**

Answer: Budget proposals that generate significant Part A savings and thereby help extend the life of the Trust Fund include proposals that support delivery system reform, promote efficient care, and align payments more closely with costs of care in both traditional Medicare and Medicare Advantage.

In addition, the revenue proposal, "Rationalize Net Investment Income and Self-Employment Contributions Act (SECA) Taxes," will also help extend the life of the Medicare Trust Fund. The proposal would ensures that all business income of high-income taxpayers is subject to the 3.8 percent net investment income tax (NIIT), while dedicating all new and current tax revenue from the NIIT to Medicare's Hospital Insurance Trust Fund.

4. **How much, in total and year-by-year, is needed to extend solvency for 15 years?**

Answer: During the 10-year budget window, the FY 2017 Budget's Medicare legislative proposals will save a net $419 billion (over a third of which would impact spending from the Hospital Insurance Trust Fund), while the net investment income tax proposal would dedicate over $500 billion to the Hospital Insurance Trust Fund. While the Budget projects savings over a 10-year period, savings from these proposals would grow over time and would be sufficient to extend solvency of the Part A Trust Fund by over 15 years.

(Dollars in Millions, negative numbers reflect savings)

	FY 2017	5 Years FYs 17-21	10 Years FYs 17-26
Total Medicare Legislative Savings Proposals (Parts A, B, C, and D)	(3,729)	(98,215)	(419,438)
Rationalize Net Investment Income and Self-Employment Contributions Act Taxes (Effects on the Hospital Insurance Trust Fund)	(389)	(194,215)	(524,774)
Total	(4,118)	(292,430)	(962,212)

Questions for Representative Holding of North Carolina:

Secretary Burwell, I understand that you heard from North Carolina[1]s Insurance Commissioner earlier this month. According to Commissioner Goodwin[1]s letter to you, he is [3]highly concerned[2] that [3]insurers may withdraw from the individual market in North Carolina altogether.[2] In North Carolina, there are only three Qualified Health Plans (QHPs), with the largest covering over two-thirds of the market. They have been approved for an average rate hike of 32.5 percent for 2016.

1. **As insurers privately discuss whether to continue to raise rates another 30% or pull out of the market entirely, how would you explain to North Carolinians that the market is working for them?**

Answer: HHS' priority is to provide Marketplace customers with access to quality, affordable coverage. In the years since the passage of the Affordable Care Act, we have seen increased competition among health plans and more choices for consumers.[1] During the third Marketplace Open Enrollment, nine out of ten returning customers were able to choose from three or more issuers for 2016 coverage, up from seven in ten in 2014. In North Carolina specifically, 74 percent of consumers had the option to purchase coverage for $75 per month or less after the advance premium tax credit[2].

[1] www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html
[2] https://aspe.hhs.gov/sites/default/files/pdf/172176/2016HealthInsurance.pdf

At the end of open enrollment in January, about 12.7 million Americans, including 613,487 North Carolinians, selected or were automatically reenrolled in affordable, quality health plans for 2016 coverage through the Marketplaces.[3] Based on analysis through late December 2015, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit for the 2016 plan year.

As for the rates in North Carolina, ACA Marketplaces help consumers shop around for the best deal. Marketplace consumers can purchase any available plan regardless of health conditions, and tools such as the doctor lookup and out-of-pocket cost calculator help them find the plan that meets their needs. Last year, 2.39 million returning HealthCare.gov consumers, more than 40%, switched plans. They saved an average of $42 per month, or about $500 annually.[4] In contrast, average rate changes reported in rate filings assume that all consumers stick with their current health insurance plan. In particular, they assume that no consumers enroll in any new plans offered for 2017, even though new plans frequently offer lower prices. This doesn't reflect reality, given that a large share of returning Marketplace consumers switched plans last year.

In addition, preliminary rates are not final rates. Preliminary rates often change significantly before being finalized. In particular, they are subject to state regulator review, which led to $1.5 billion in savings for consumers in 2015. Last year, final rates in some states were below proposed rates. Lastly, it is important to remember that tax credits go up along with premiums. 85% of Marketplace consumers receive tax credits, which are designed to protect consumers from premium increases and help make coverage affordable. Tax credits increase if the cost of the second lowest-cost silver, or benchmark, plan goes up. So if all premiums in a market go up by similar amounts, 85% of Marketplace consumers in that market will not necessarily pay more because their tax credits will go up to compensate. Rate increases reported in the rate filings do not account for tax credits.

Moving forward, HHS is eager to build on the progress in reducing the number of uninsured Americans – an estimated 17.6 million Americans gained coverage as the Affordable Care Act's coverage provisions have taken effect,[5] and the Nation's uninsured rate is below 10 percent for the first time since data collection began over five decades ago. And because of the ACA, Americans across the country have access to better insurance, no matter where it's purchased.

Six years ago, if you were one of America's 13.7 million cancer survivors, or the millions living with a chronic disease, it was almost impossible to get health insurance. Today, no one can be denied coverage because of a pre-existing condition.

[3] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-04.html
[4] http://www.hhs.gov/blog/2016/04/12/premiums-last-year-much-lower-than-initial-rates-suggested.html
[5] https://aspe.hhs.gov/health-insurance-coverage-and-affordable-care-act-aspe-issue-brief-september-2015

Six years ago, having insurance didn't necessarily mean you would get any help paying for basic care. Today, 137 million Americans with private insurance have preventive care at no extra cost.

And six years ago, families had to worry that their insurance would stop paying claims when they needed it most. Even if you never missed a premium payment, a major illness could mean bankruptcy. Today, annual and lifetime caps on most benefits are gone and families are protected.

As you know, individuals are able to purchase health insurance outside of the annual open enrollment period if they prove to HHS that they have experienced a [3]qualifying life event.[2] Insurers have told HHS that consumers enrolled through special enrollment periods are utilizing up to 55 percent more services than those consumers that enrolled during the open enrollment period. I have heard from insurers in my state that these special enrollment periods are [3]being gamed.[2] Without confidence that HHS will properly process or deny special enrollment period applications, insurers may choose to not offer their products on the exchange.

2. **What actions is HHS taking to prevent individuals from [3]gaming the system[2] and what actions is the agency taking to reassure insurers that this is not taking place?**

Answer: Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- clarifying language to make the rules of the road are clear to everyone,
- reviewing all SEPs and eliminating those that are no longer necessary, such as:
    - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy
    - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
    - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
    - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
    - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
    - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and

- providing stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes.

We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.

Question from Representative Dold of Illinois:

Secretary Burwell, I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk products consumed by young children up to three years of age. My understanding is that this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the U.S. dairy industry that need to be further examined.

- **Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?**

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,[6] and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical

[6] As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf (Accessed March 14, 2016).

comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

Questions from Representative Meehan Pennsylvania:

President Obama promised that Obamacare will be affordable. The fact is that individuals and families have been subject to double-digit increases in premiums and deductibles. The premiums for the second-lowest priced silver plan increased by nearly 11% in Pennsylvania between 2015 and 2016. This is consistent with the average national premium increase of 11.3% for a silver tier plan. Nationally, the average deductibles for the lowest-cost Obamacare plans increased from 2015 to 2016 by 10.6% for individuals and 10% for families. A higher deductible means higher out-of-pocket expenses for individuals and families. And as a result, individuals are putting off medical care. Republicans are working on delivering on the promise of expanding access to affordable health care insurance coverage.

1. **What am I supposed to tell my constituents about why Obamacare is increasingly unaffordable?**

Answer: The Affordable Care Act takes significant steps towards expanding coverage and improving access to health care while also improving the quality and affordability of health care for all Americans. It strengthens the private health insurance market and extends financial assistance to moderate-and low-income Americans to help make health insurance coverage more affordable. For example, for consumers in the 38 states using the healthcare.gov platform, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit with an average value of $294 per person per month[7]. In fact, most people can find monthly premiums for $75 or less, after financial assistance.

ACA Marketplaces help consumers shop around for the best deal. Marketplace consumers can purchase any available plan regardless of health conditions, and tools such as the doctor lookup and out-of-pocket cost calculator help them find the plan that meets their needs. Last year, 2.39 million returning HealthCare.gov consumers, more than 40%, switched plans. They saved an average of $42 per month, or about $500 annually.[8] In contrast, average rate changes reported in rate filings assume that all consumers stick with their current health insurance plan. In particular, they assume that no consumers enroll in any new plans offered for 2017, even though new plans frequently offer lower prices. This doesn't reflect reality, given that a large share of returning Marketplace consumers switched plans last year.

[7] https://aspe.hhs.gov/pdf-report/health-insurance-marketplaces-2016-average-premiums-after-advance-premium-tax-credits-38-states-using-healthcaregov-eligibility-and-enrollment-platform
[8] http://www.hhs.gov/blog/2016/04/12/premiums-last-year-much-lower-than-initial-rates-suggested.html

Lastly, it is important to remember that tax credits go up along with premiums. 85% of Marketplace consumers receive tax credits, which are designed to protect consumers from premium increases and help make coverage affordable. Tax credits increase if the cost of the second lowest-cost silver, or benchmark, plan goes up. So if all premiums in a market go up by similar amounts, 85% of Marketplace consumers in that market will not necessarily pay more because their tax credits will go up to compensate. Rate increases reported in the rate filings do not account for tax credits.

I am concerned that HHS is proposing Medicare policies that are not patient-centered and would likely drive up Medicare spending. For example, the Administration proposes to implement a $100 per episode co-payment for home health services that are not preceded by an inpatient hospital stay for all new beneficiaries. Despite the Administration's estimate of cost savings, the Medicare Payment Advisory Commission (MedPAC) has highlighted that a disadvantage of requiring beneficiary cost-sharing for home health is that it could encourage Medicare beneficiaries to use more expensive post-acute care settings. In the 1960s, Medicare required a co-payment for home health services. In repealing the co-pay in 1972, Congress recognized that the co-payment resulted in shifts to more costly settings.

2. **Why would the Administration propose a policy that Congress has already rejected?**

Answer: Thank you for raising this important issue. This proposal is consistent with Medicare Payment Advisory Commission (MedPAC) recommendations to introduce a copayment for these services. MedPAC notes that beneficiaries without a prior hospitalization account for a rising share of home health episodes and that adding beneficiary cost sharing for home health care could be an additional measure to encourage appropriate use of home health services. Since many of these services are funded by Medicare Part B, MedPAC notes that decreases in home health spending growth would reduce Part B premiums.

While home health utilization and spending have grown over the past decade, home health services represent one of the few areas in fee-for-service Medicare that does not currently include beneficiary cost-sharing. Adding cost-sharing is expected to encourage beneficiaries to consider the appropriate use of home health services.

This proposal has appropriate safeguards to make sure that its implementation will not unfairly burden beneficiaries or restrict access to care. We appreciate your concern and would be happy to answer additional questions or provide a staff-level briefing.

The 12 years of data exclusivity for biologics may be among the few areas of bipartisan agreement in the Affordable Care Act. I am disappointed that the Administration undercut U.S. law by negotiating data exclusivity of less than 12 years in the Trans-Pacific Partnership and is now proposing to reduce the market

exclusivity period to 7 years. While the Administration suggests that reducing exclusivity prevents high drug prices, the Administration fails to acknowledge the reduction's potential effect on innovation.

3. **Why does the Administration reject the ACA's carefully negotiated 12 years of data exclusivity and what calculation has HHS made as to the impact on the innovation of novel biologics?**

Answer: The budget proposal to reduce the exclusivity period to 7 years in the United States is one of several proposed reforms designed to increase access to generic drugs and biologics.

With regard to the Trans-Pacific Partnership (TPP) Agreement, the U.S. opening proposals on pharmaceutical intellectual property provisions were based on existing U.S. law, under which the current standard for market exclusivity for biologic drugs is 12 years. Biologics exclusivity was one of the most challenging issues in the TPP negotiations. The Administration fought hard for an outcome as close to U.S. law as possible. The result was a negotiated compromise that guarantees 8 years of protection for biologics by our TPP partners. This level of protection for biologics still spurs innovation in biologic medicine, which offers great potential for new treatments and cures.

I am concerned that the ACA's reduction in Disproportionate Share Hospital (DSH) payments minimizes the correlation between participation in the Medicare DSH program and higher Medicare costs for urban hospitals with more than 100 beds like those that serve and employ individuals in my District. The problem is further exacerbated by CMS' switch to using the S-10 worksheet to calculate uncompensated care. My understanding is that the S-10 is not consistent with how hospitals report data. One analysis finds that Pennsylvania hospitals in the aggregate would see a 43.6% loss in payments as a result of the switch to S-10. If CMS is interested in capturing data more broadly, the Agency must ensure that it does not cherry pick data points to paint the picture it wants to see. In seeking to know what supplemental payments a hospital receives, CMS should not be blind to a hospital's Medicare losses.

4. **What is the status of CMS' efforts to implement the S-10?**

Answer: The Affordable Care Act modified the method for computing Medicare DSH adjustments, beginning in 2014, and for each subsequent fiscal year. Under this provision, hospitals eligible to receive Medicare DSH payments receive 25 percent of the amount they would have received under the statutory formula for Medicare DSH payments previously in effect. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid to Medicare DSH hospitals based on their share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period. In addition, the Secretary has the

authority to estimate uncompensated care based on appropriate data, including alternative data where the Secretary feels that proxy data is a better estimate for the costs of treating the uninsured.

In FY 2014, CMS determined that Worksheet S-10 of the Medicare cost report could potentially provide the most complete data for Medicare hospitals. For a full report on the potential data sources considered, please visit: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html. At the time, CMS also noted that Worksheet S-10 is a relatively new data source that has been used for specific payment purposes only in relatively restricted ways (for example, to provide a source of charity care charges in the computation of EHR incentive payments).

Because of concerns regarding variations in the data reported on Worksheet S-10 of the Medicare cost report and the completeness of these data, CMS did not propose to use data from the Worksheet S-10 to determine the amount of uncompensated care for FY 2014. However, since FY 2014 hospitals have been on notice that Worksheet S-10 could eventually become the data source for CMS to calculate uncompensated care payments. CMS continues to believe reporting on Worksheet S-10 will improve over time particularly in the area of charity care reporting, which is already being used and audited for payment determinations related to the EHR Incentive Program.

CMS has stated that they may proceed with a proposal to use data on the Worksheet S-10 to determine uncompensated care costs in the future. The Worksheet S-10 could ultimately serve as an effective source of more direct data regarding uncompensated care costs for purposes of determining the allocation of uncompensated care payments once hospitals are submitting accurate and consistent data through this reporting mechanism. In the interim, CMS is committed to taking steps such as revising and clarifying cost report instructions, as appropriate.

As you know, 43 colleagues joined me in sending a letter to CMS outlining concerns with the way the Agency is implementing Medicare payment reform for clinical laboratories as required by the Protecting Access to Medicare Act of 2014. We are currently awaiting a response from CMS. I'm hoping you can address several concerns.

5. **Why did CMS exclude a number of laboratories from the reporting process? Wouldn't you expect this exclusion to skew the market data resulting in Medicare rates that are not reflective of market rates?**

Answer: We appreciate your concerns. As CMS's January 8th response noted, we are in active rulemaking on this topic and cannot provide much comment, but will be sure your comments are considered as CMS prepares the final rule. If you did not receive the letter, please let us know and we would be happy to send you a copy. In October 2015, CMS published a proposed rule to implement section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare

payment rates. In the proposed rule, CMS proposed to define the term "laboratory" according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. We also addressed how to meet the statutory requirement that an "applicable laboratory" receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, we proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

We are currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an "applicable laboratory". We will carefully consider those comments in developing a final rule implementing PAMA.

6. **In light of clear statutory language, why did CMS exclude "proteins" from the biomarkers that an Advanced Diagnostic Laboratory Test must be able to analyze? What is the status of implementation and has the Agency made any adjustments to the implementation timeline?**

Answer: The Protecting Access to Medicare Act of 2014 (PAMA) defines an Advanced Diagnostic Laboratory Test (ADLT) as "a clinical diagnostic laboratory test covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner)". To qualify as an ADLT (which receives special treatment under the new payment system established by PAMA), the test must also meet one of three additional criteria, including (as one option) that the test is "an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result."

In its proposed rule published in October 2015, CMS considered how best to operationalize this complex statutory definition. CMS subsequently received many comments on the proposed rule including comments on the proposed definition of an ADLT. We are currently reviewing those public comments and we will carefully consider them in developing a final rule implementing PAMA.

Rep. Diane Black and I introduced legislation, the Federal Exchange Data Breach Notification Act of 2015 (H.R.555), last year to require the government to notify consumers if their information is compromised on the Obamacare exchanges. We remain concerned about the potential for breaches.

7. **Could you provide an update regarding any improvements that the Department of Health and Human Services (HHS) has made to the security and privacy controls for the Obamacare Federal Data Hub?**

Answer: The privacy and security of consumers' information is a top priority. When consumers fill out their online health care Marketplace applications, the information they are providing is protected by stringent security controls. While no system is immune from attempted attacks or intrusions, CMS continually maintains and strengthens the security of HealthCare.gov and its supporting systems. HHS conducts continuous monitoring using a 24/7, multi-layer IT professional security team, third-party penetration testing, and a change management process that includes ongoing testing and mitigation strategies implemented in real time. To date, no person or group has maliciously accessed personally identifiable information through HealthCare.gov or supporting systems.

HHS has taken significant steps and implemented robust security controls to protect the security and privacy of the systems and connections supporting HealthCare.gov, including the Hub. HHS developed these systems consistent with federal statutes, guidelines, and industry standards that help safeguard the security, privacy, and integrity of the systems and the data that flow through them. HealthCare.gov and the Hub have been determined to be compliant with the Federal Information Security Modernization Act of 2014 (FISMA), based on standards promulgated by the National Institute of Standards and Technology (NIST). Marketplace systems are also in compliance with all the relevant privacy and security statutes, including the Privacy Act of 1974.

The Hub and its associated systems are protected via layered security (i.e. Defense in Depth) to mitigate information security risk, including penetration testing, which happens on an ongoing basis using industry best practices to appropriately safeguard consumers' personal information and agency data. As part of the ongoing testing process, and in line with federal and industry standards, any open risk findings are appropriately addressed using risk mitigation strategies and implementing compensating controls. The security of the system is also monitored by sensors and other tools to deter and prevent unauthorized access.

8. What funding does HHS devote to cybersecurity protection for the exchanges and more broadly?

Answer: The Department dedicates resources to support the responsibility of securing millions of individuals' personal health information, conducting highly sensitive biodefense work, reviewing new drug applications and clinical trial data, and issuing more grants than any other federal entity. In FY 2016, HHS is dedicating a total of $51 million to support cybersecurity activities to ensure that the program has resources to appropriately plan, mitigate, and address cyber threats. The FY 2017 President's Budget maintains these investments. In addition to these resources, HHS agencies request additional support for cybersecurity through their programs. In the FY 2017 President's Budget, CMS requested funding to enhance cybersecurity by completing a transition to an enterprise approach for managing information security and privacy.

Health Insurance Marketplace cybersecurity is part of CMS' overall investment in Information Technology for the Marketplaces. The FY 2017 Budget requests a Marketplace IT program level of $657 million. This investment supports systems integration, testing, and security across the Marketplaces to ensure integration and testing of new code, and security standards for consumer and issuer data. CMS has implemented

security controls and reviews, including ongoing penetration testing and automated scanning, consistent with FISMA requirements and industry best practices. As part of the ongoing testing process, and in line with federal and industry standards, any open risk findings are addressed with risk mitigation strategies and compensating controls. Marketplace IT systems are continuously monitored by sensors and other tools to deter and prevent unauthorized access.

The Centers for Medicare and Medicaid Services (CMS) finalized its Medicare Part B reimbursement policy for biosimilars to combine all biosimilars into one average sales price calculation and payment code. Effectively, the payment policy treats biosimilars as if they are generics. Biosimilars are not copies of one another like generics.

9. What is CMS' rationale for the blended payment rate for biosimilars?

Answer: Biosimiliars hold great promise for all Americans, including Medicare beneficiaries, and CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace. Competition fosters innovations that redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries – improving quality, price, and access.

While we appreciate that there are differences between multiple source drugs and biosimilars, from a payment policy perspective, it is reasonable to treat them similarly. They both have significant similarities with their predecessor product (a reference product for biosimilars and an innovator product for generics) and they are both approved through an abbreviated pathway. Further, we believe that biosimilars and multiple source drugs will have similar marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product.

Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. To the contrary, we believe there is a strong need for lower cost alternatives to high cost biologicals, and the statute provides an incentive for the development of the biosimilars market by providing for reimbursement that includes a 6 percent add-on of the reference product's Average Sales Price.

Questions from Representative Price of Georgia:

<u>MACRA Implementation</u>

Secretary Burwell, in a review of the proposed FY 2017 Budget for the Centers for Medicare and Medicaid Services (CMS), I didn't see any discussion regarding how CMS will be distributing to medical societies the resources provided in MACRA for quality measure development and other quality related activities. I believe that

Congress provided $15 million per year starting in FY 2016 and to date none of that money has been made available.

1. **Can you share with the Committee HHS' plans for getting this money to the provider community for measure development activities?**

Answer: MACRA provides CMS with $15 million annually from FY 2015 to FY 2019 to develop a framework for future clinician quality measurement development to support the Merit-based Incentive Payment System and Alternative Payment Models. To meet the requirements of the statute, CMS posted the draft Measure Development Plan on December 18, 2015, with a public comment period through March 1, 2016. Per the statute, the final plan will be posted in May, followed by updates thereafter as appropriate. This plan will be used to guide the priority areas for measure development.

CMS recognizes the importance of measure development as we work to implement the provisions of MACRA. The process of preparing a measurement proposal concept, seeking bids, and assessing competitive bids will soon be underway. CMS has actively engaged with specialty societies to learn about their interests in the funding, and is synthesizing the results of these engagement sessions in order to spend contract dollars in a way that meets the needs of these organizations.

2. **The President's Budget discusses the implementation of MACRA and alternative payment models being developed. What plans do HHS and CMS have in place to ensure that every alternative payment model developed by a medical society that meets the criteria for being a qualified alternative payment model gets implemented and is ready for physicians to participate in starting January 1, 2019?**

Answer: MACRA established a new independent advisory committee, the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The PTAC meets on a periodic basis to review physician-focused payment models submitted by individuals and stakeholder entities and prepare comments and recommendations on proposals that are received, explaining whether models meet criteria for physician-focused payment models.

We look forward to receiving recommendations for new physician-focused payment models. We will need stakeholder engagement with the PTAC, including physicians and other clinicians, to suggest well designed, robust models that could meet the statutory criteria to be an eligible APM.

The PTAC currently anticipates meeting on a quarterly basis to assess physician-focused payment model proposals, but the frequency of meetings may change depending on the number and complexity of proposals received. All meetings will be public, with timely, advance notice of meetings provided through the Federal Register. We encourage stakeholders to attend these meetings and provide comments and input to the PTAC on

the proposals; remarks may be made during the public comment portion of the meetings or comments may be submitted in writing.

After reviewing proposals, the PTAC will prepare comments and recommendations regarding whether the models meet the physician-focused payment model criteria established by HHS. The PTAC will submit its comments and recommendations to the Secretary, who will then review them and post a detailed response to them on the CMS website.

3. **How is the money available under the Centers for Medicare and Medicaid Innovation (CMMI) being used to provide technical assistance, data support, and review opportunities for physician societies that are developing alternative payment models for MACRA?**

Answer: Congress provided funding in MACRA for CMS for technical assistance to small practices, rural practices, and practices in medically underserved health professional shortage areas. This technical assistance could be provided by entities such as regional extension centers and regional health collaboratives to offer guidance and assistance to physicians and other clinicians.

The technical assistance is to focus on the performance categories under the Merit-based Incentive Payment System (MIPS), helping to make it as seamless as possible for these clinicians and practices to comply with MIPS requirements and helping interested practices transition to implementation of and participation in an alternative payment model (APM).

We requested feedback from the physician and broader clinician community last year on how best to implement this technical assistance. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community, including discussing the role that the Centers for Medicare and Medicaid Innovation (CMMI) can play in developing alternative payment models for MACRA. Currently, in developing and testing payment and service delivery models, CMMI is providing opportunities for stakeholders, including members of physician societies, to gain experience with new payment models and to participate in forums like the Health Care Payment Learning and Action Network.

4. **Is CMMI working to develop APMs under MACRA? Will the Comprehensive Care for Joint Replacement Model (CJR), a new episode-based payment model for lower extremity joint replacement, be considered an APM under MACRA?**

Answer: MACRA established a particular definition of alternative payment models (APMs) and established what qualifies as an "eligible APM," for purposes of evaluating whether an EP is a qualifying APM participant (QP) for a year. QPs receive a payment incentive and are exempt from the Merit-Based Incentive Payment System for the year.

While creating this new category of eligible APMs provides for promising incentives for a growing number of EPs in the future, we expect the initial years to be ones of development as we apply lessons learned and continue to refine the program. The statute creates a high bar for eligible APMs. Many currently existing APMs – at the Innovation Center and in the private sector – are not likely to meet all these requirements, but some will. We will continuously search for opportunities to expand the range of options for participation in eligible APMs within the contours of the statute. In keeping with the statute, it is our intent to align the MIPS and the APM incentives to the extent feasible, thus allowing maximum flexibility for physicians and other clinicians who are not yet ready to participate in eligible APMs to participate in MIPS and then migrate to eligible APMs when they are ready.

As we move forward with MACRA implementation, we will continue to gather and incorporate feedback from stakeholders as we promote additional physician-focused APMs and work to define the details of the eligible APM criteria contained in statute. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

CMMI

5. **It should come as no surprise that we take issue with CMMI's broad interpretation of authority. Are we to anticipate that CMMI will continue to exploit the authority granted under Section 1115A by promulgating additional mandatory demos where patients are thereby used as test subjects? How will CMMI identify the patient population and services to be targeted in future demos?**

Answer: Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. While I appreciate your concern, the statute does not require that models be voluntary, but rather gives the Secretary discretion to design and test models that meet certain requirements as to spending and quality.

Models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. In addition, the Secretary must focus on models expected to reduce program costs while preserving or enhancing the quality of care. All models include monitoring and evaluation of patient care. Section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, but the Secretary is not limited to those models. The Innovation Center will continue to use these statutory criteria, including input from interested parties, for selecting and designing future models.

Section 1115A requires that models which fail or are expected to fail to improve the quality of care within current spending or reduce spending while maintaining the quality of care be terminated or modified.

6. **What exactly are the processes used by CMS to evaluate and modify models, and how does CMS deem a model to be worthy of termination?**

Answer: Every 1115A model has a rigorous, rapid-cycle, evaluation conducted by an independent team that unfolds concurrently with model implementation. In every model evaluation, we strive to determine the impact of the innovation on patient and provider experiences, outcomes and quality of care, and program expenditures. While each model is different and requires a customized evaluation approach, common components include: regular surveys of beneficiary experience of care, analysis of claims-based utilization and quality of care outcomes, and qualitative data collection, such as patient and caregiver focus groups. We make sure that our models are well designed – and we use all appropriate scientific and statistical methods to study the impact of the model test relative to what would have happened in the absence of that model test.

We are required to terminate or modify an Innovation Center model unless the model is expected to improve the quality of care without increasing spending, reduce spending without lowering the quality of care, or both improve the quality of care and reduce spending. CMS uses these criteria to determine if a model should be terminated or modified based on the data available from the model evaluations and other sources.

CJR-Focused Questions:

7. **The Comprehensive Care Joint Replacement model is expected to capture nearly 800 acute care hospitals with at least 120,000 joint replacements a year. What data did CMMI rely on in developing the CJR model in order to conclude that the CJR model will lead to improved care?**

Answer: The CJR model is informed by other models and demonstrations currently and previously conducted by CMS and will explore additional ways to enhance coordination of care and improve the quality of services through bundled payments. Medicare tested innovative approaches to paying for orthopedic services in the 3-year Medicare Acute Care Episode (ACE) demonstration. CMS is currently testing additional approaches under the Bundled Payments for Care Improvement (BPCI) initiative. Both of these models informed the design of the CJR model.

CMS will provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Furthermore, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the

hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period.

In addition, because we are proposing to incorporate regional pricing data in the creation of prices for the CJR model, we will provide comparable aggregate expenditure data available for all claims associated with MS DRGs 469 and 470 during an episode period for the census region in which the participant hospital is located. We believe that making these data available will enhance participating hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model.

8. How will CMMI monitor the effects of CJR throughout the duration of the program?

Answer: As with all Innovation Center models, during the CJR model, CMS will monitor and evaluate the impact of the model to guard against any unintended consequences that might negatively impact beneficiaries. With respect to monitoring for access to care, CMS will apply their existing authority and tools to monitor for overutilization and underutilization of care under the CJR model. These tools include data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary. With respect to monitoring for quality of care, CMS will use their existing authority to audit claims and services, use the Quality Improvement Organizations to assess for quality issues, use CMS authority to investigate allegations of patient harm, and to monitor the impact of the quality metrics for the model. Beneficiaries also have the ability to report concerns about the model to Quality Improvement Organizations and through 1–800–MEDICARE. Finally, CJR model participants will also be monitored for compliance with all existing rules and regulations.

The evaluation will include both quantitative and qualitative data and will use a variety of methods and measures in assessing quality. This will include claims based measures such as increases in readmissions and ER visits, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) satisfaction and care experience measures, and functional performance change scores from the required patient assessment instruments in Home Health Agencies (HHAs) and Skilled Nursing Facilities (SNFs). In addition, CMS plans for the evaluation to include a beneficiary survey that will be used to assess the impact of the CJR model on beneficiary perceptions of access, satisfaction, pain, mobility, and other relevant functional performance measures.

9. Will CMMI be able and ready to halt the demo immediately if shown to reduce the quality of care?

Answer: As concerns are identified, CMS can initiate audits and corrective action under existing authority. In addition, under Section 1115A(b)(3)(B) of the Social Security Act, the Secretary is required to terminate or modify an Innovation Center model unless the model is expected to improve the quality of care without increasing spending, reduce

spending without lowering the quality of care, or both improve the quality of care and reduce spending. If during the course of testing the CJR model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

10. **Current information from conversations with several BPCI conveners for hospitals and hospital awardees indicates a large number of hospitals, or systems, have not realized favorable reconciliations for CY2014 or Q1-Q2 2015. Given the rapid pace of the CJR start date and the extremely limited time participating hospitals have to obtain, analyze, decipher, and make decisions from the historical data, how do you expect the CJR model to be a success?**

Answer: The CJR model has the potential to improve quality in four ways. First, the model adopts a quality first principle where hospitals must achieve a minimum level of episode quality before receiving reconciliation payments when episode spending is below the target price.

Second, higher episode quality, considering both performance and improvement, may lead a hospital to receive quality incentive payments based on the hospital's composite quality score, a summary score reflecting hospital performance and improvement on two measures: one related to the complication rates for elective hip or knee replacements and the other measuring patient experience of care.

The composite quality score also takes into consideration a hospital's submission of patient-reported outcomes and limited risk variable voluntary data.

Third, in addition to quality performance requirements, the model incentivizes hospitals to avoid expensive and harmful events, which increase episode spending and reduce the opportunity for reconciliation payments.

Fourth, CMS provides additional tools to improve the effectiveness of care coordination by participant hospitals in selected Metropolitan Statistical Areas. These tools include: 1) providing hospitals with relevant spending and utilization data; 2) waiving certain Medicare requirements to encourage flexibility in the delivery of care; and 3) facilitating the sharing of best practices between participant hospitals through a learning and diffusion program.

The CJR model includes certain financial safeguards for participant hospitals. There is no repayment responsibility in performance year 1, a stop-loss limit of 5 percent in performance year 2, a stop-loss limit of 10 percent in performance year 3, and a stop-loss limit of 20 percent in performance years 4 and 5 for participating hospitals other than rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals. The stop-loss limit for these hospitals will be at 3 percent in performance year 2 and 5 percent in performance years 3 through 5. A parallel approach has been finalized for the stop-gain limits to provide proportionately similar protections to CMS and

hospital participants, as well as to protect the health of beneficiaries. The CJR model also gradually phases in repayment responsibility with a reduced discount percentage for repayment responsibility in years 2 and 3.

CMS will also provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Moreover, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period. In addition, because we are proposing to incorporate regional pricing data in the creation of prices for the CJR model, we will provide comparable aggregate expenditure data available for all claims associated with MS DRGs 469 and 470 during an episode period for the census region in which the participant hospital is located. We believe that making these data available will enhance participating hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model.

11. Performance estimates of hospitals in CJR markets (using available data from CMS and BPCI historical and performance period data from the same or similar markets and estimates of trend factors) indicate that nearly 75% (579 of 794 hospitals) will show annual losses under CJR (many in the millions of dollars) if they are unable to dramatically affect post-acute care service utilization and achieve provider alignment across the entire care continuum, a function not traditionally performed by hospitals or physicians. Given the complexity of implementing effective care redesign under CJR, do you anticipate a percentage of hospitals to stop providing hip and knee replacements because this mandatory program has the potential to create a cataclysmic financial downfall?

Answer: The model's goal is to give hospitals a financial incentive to work with physicians, home health agencies, skilled nursing facilities, and other providers to make sure beneficiaries get the coordinated care they need. Patients, hospitals, physicians, and post-acute care providers all stand to gain from the successful implementation of the CJR model. By improving care coordination throughout the episode, unnecessary care can be reduced, and quality outcomes improved. There will be an opportunity for hospitals to earn more through partnerships with physicians and post-acute care providers as care coordination is improved, and opportunities for hospitals to share these funds with physicians and post-acute care provider collaborators in care redesign. We anticipate hospitals will continue to serve patients needing hip and knee replacements and improve collaboration with other post-acute providers in the community leading to improved outcomes for beneficiaries.

Furthermore, the CJR model includes certain financial safeguards for participant hospitals. There is no repayment responsibility in performance year 1, a stop-loss limit of 5 percent in performance year 2, a stop-loss limit of 10 percent in performance year 3, and a stop-loss limit of 20 percent in performance years 4 and 5 for participating hospitals other than rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals. The stop-loss limit for these hospitals will be at 3 percent in performance year 2 and 5 percent in performance years 3 through 5. A parallel approach has been finalized for the stop-gain limits to provide proportionately similar protections to CMS and hospital participants, as well as to protect the health of beneficiaries. The CJR model also gradually phases in repayment responsibility with a reduced discount percentage for repayment responsibility in years 2 and 3.
CMS will also provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Moreover, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period.

In addition, because we are proposing to incorporate regional pricing data in the creation of prices for the CJR model, we will provide comparable aggregate expenditure data available for all claims associated with MS DRGs 469 and 470 during an episode period for the census region in which the participant hospital is located. We believe that making these data available will enhance participating hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model.

CMMI and ACOs

12. The Pioneer ACO program appears to be your most "successful" program judging by the fact that it was the only program you chose to expand. Albeit there is no indication that the Pioneer ACO model met the statuary criteria for expansion. Nonetheless, 13 of 32 ACOs, approximately 40%, dropped out of Pioneer after just one year. Is this a program capable of sustaining itself?

Answer: The Pioneer ACO Model is the first model designed and tested by CMMI to be certified for expansion by the CMS Office of the Actuary and the Secretary of HHS. Under the Affordable Care Act, the Secretary has the authority to expand an Innovation Center model in duration and scope for Medicare if: 1) an expansion is expected to reduce spending without reducing the quality of care or improve the quality of care without increasing spending 2) the CMS Chief Actuary certifies that an expansion would

reduce or maintain net program spending and 3) an expansion would not deny or limit the coverage or provision of benefits to Medicare beneficiaries. The CMS Office of the Actuary has reviewed the Pioneer ACO Model's early independent evaluation results, as well as conducted its own additional analyses, and concluded that an expansion of the Pioneer ACO Model as it existed in the first two performance years would reduce net program spending under Medicare. The Secretary has also determined that an expansion of the Pioneer ACO Model would maintain or improve quality and would not deny or limit coverage or provision of benefits, thereby allowing the Secretary to expand this model.

In terms of sustainability for the Pioneer ACO Model, the model began on January 1, 2012 as a five-year model developed by CMMI to test whether alternative design elements might enhance ACO effectiveness and ultimately inform policy changes to improve the Shared Savings Program by means of future rulemaking. The model concludes in 2016. Regarding the Pioneer ACOs that chose to leave the model, CMS always expected that a subset of Pioneer ACOs would leave the model over time. CMS respects the need for individual organizations to make decisions that are most appropriate for their circumstances but we are encouraged that several of the Pioneer ACOs transitioned to being participants in the Medicare Shared Savings Program and the Next Generation ACO Model. These developments bolster CMS' confidence that incorporating elements of the Pioneer ACO Model into the Shared Savings program will help those alternative payment arrangements improve outcomes for beneficiaries and Medicare, as well as increase provider participation in them. As we learn through demonstrations and stakeholder comment what works well in the model= subsequent rulemaking for the Shared Savings Program will be informed by lessons learned from our experience.

13. <u>Total spending on all CMMI experiments to date has amounted to $4.335 billion.</u> Only one program has been selected for expansion, yet it generates minimal savings. How do you justify wasting billions of taxpayer funds?

Answer: In 2014 alone, Medicare ACOs improved quality of care and saved an estimated $411 million. From 2010 to 2014, there was a 17 percent decline in patient harm resulting in an estimated 2.1 million fewer hospital-acquired conditions, an estimated 87,000 fewer patients dying in hospitals and nearly $20 billion in health care costs saved — likely the result of various programs that support and incentivize hospitals to share best practices for reducing avoidable harm. While there's still more work to do, the new programs implemented and models being tested are providing the tools needed to sustain the historic slowdown in health care cost growth we've seen since 2010.

The Innovation Center's portfolio of models has attracted participation from a broad array of health care providers, states, payers, and other stakeholders, and serves Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries in all 50 states, the District of Columbia and Puerto Rico. Over 4.7 million Medicare, Medicaid, and CHIP beneficiaries are or soon will be receiving care furnished by the more than 61,000 providers participating in Innovation Center payment and service delivery models. Beyond the impact for these beneficiaries, Innovation Center models

are impacting tens of millions of additional Americans by engaging thousands of other providers, payers, and states in model tests and through quality improvement efforts that extend across the country. Innovation Center models are making important contributions towards building a health care delivery system health care system that leads in innovation, delivers affordable, high-quality medicines, and results in healthier people. CBO recently estimated in a report dated July 30, 2015 that the work of the Innovation Center would yield $38 billion in savings over the next ten years (2016 to 2025).

Problems with EHRs

14. How much federal money has been used to invent implementation of EHRs?

Answer: The American Recovery and Reinvestment Act (ARRA) appropriated $2 billion to the Office of the National Coordinator for Health Information Technology (ONC) to implement the HITECH Act. ONC used its ARRA funds to support the development of a national health IT infrastructure that enabled providers to leverage health information to improve the quality and efficacy of the care they deliver to their patients. The $2 billion was a one-time influx of funding. Outside of this funding, ONC's annual budget has been approximately $60 million since 2007. The Center for Medicare and Medicaid Services (CMS) EHR Incentive Programs provided payments to eligible professionals and hospitals to adopt, implement, and demonstrate meaningful use of certified EHR and have paid approximately $33.6 billion in incentive payments. As with all our funding, we are committed to proper stewardship of taxpayer dollars.

15. Did we invent behavior that deployed EHRs before we had the right architecture to deliver on digital healthcare? Aren't we backtracking now to create the sort of interoperability and data liquidity that we should have developed as initial standards?

Answer: The EHR Incentive Programs rule and the ONC certification program have been successful in driving adoption and use of EHR technology. In the seven years since the HITECH Act was enacted, the nation has seen dramatic advancement in the use and adoption of health IT. Specifically, nearly all (97%) acute care hospitals have adopted certified health IT and three-quarters (74%) of physicians have adopted certified health IT.

ONC recognizes that collaborative commitments across government and industry are needed to address challenges for the U.S. to realize the full benefits and potential of a secure, interoperable electronic health information infrastructure that seamlessly supports the health system and provides individuals with safe, person-centered care. As adoption increases, ONC and CMS have worked together to advance standards-based interoperability, including through provisions in the fall 2015 release of the latest health IT certification rule and EHR Incentive Programs rule.

16. Aren't we challenged to get the EHR vendors to cooperate to the level beyond their own self-interests and acting toward better a national architecture that serves not only the Medicare beneficiaries, but all patients?

Answer: In its Shared Nationwide Interoperability Roadmap, ONC identified near-term actions and roles that health IT stakeholders should perform to make immediate progress and impacts with respect to interoperability. The Roadmap is a shared, industry wide set of milestones, calls to actions, and commitments that lays out a focused series of steps and activities that we need to collectively undertake to achieve interoperability and enable a learning health system. Though ONC defines a path to short term success, the Roadmap is also designed to lay out a long-term vision and was developed with extensive input from federal agencies, Congress, and health IT stakeholders, including consumers, healthcare providers, health IT developers, and public health. It provides an opportunity to improve coordination and includes a set of milestones by which we can judge progress.

The Roadmap specifically called out three specific principles: 1) supporting consumer access, 2) not blocking information, and 3) implementing federally recognized, national standards around interoperability so all products speak the same language. In February 2016, Secretary Burwell announced at the Healthcare Information and Management Systems Society (HIMSS) meeting that companies providing electronic health records to 90% of hospitals agreed to take action to implement those three commitments. Additionally, hospitals including the five largest and many others that span a total of 46 states also stepped up and agreed to these commitments. We are optimistic about this unparalleled public-private sector collaboration on interoperability.

A New Approach to Meaningful Use

17. **Most everyone agrees we need to move away from the current way of doing things – both in MU and EHR certification. Our patients and physician colleagues have joined in unison to call for serious reform. Given Administrator Slavitt's recent comments admitting that the Meaningful Use program needs reform, how specifically has ONC been advising CMS in rethinking the MU program?**

Answer: ONC and CMS have been working side by side to update the Medicare and Medicaid EHR Incentive Programs, advance the certification of health IT towards care delivery goals, and to implement MACRA.. In addition, we have been working with physician and consumer communities and have listened to their needs and concerns. For Medicare physicians and other practitioners, we will be sharing details and inviting comment on our proposal to implement the EHR requirements in MACRA as we roll out our proposed regulations this spring.

Several critical principles inform the important work of both agencies. First, we aim to reward providers for the outcomes technology helps them achieve with their patients. Second, we want to allow providers the flexibility to customize health IT to their individual practice needs. Technology must be user-centered and support physicians. Third, we need to level the technology playing field to promote innovation, including for start-ups and new entrants, by unlocking electronic health information through open APIs – technology tools that underpin many consumer applications. This way, new apps, analytic tools and plug-ins can be easily connected to so that data can be securely accessed and directed where and when it is needed in order to support patient care.

Finally, we aim to prioritize interoperability by implementing federally recognized, national interoperability standards and focusing on real-world uses of technology, like ensuring continuity of care during referrals or finding ways for patients to engage in their own care.

ONC and CMS will continue working together to prevent information blocking, improve the EHR Incentive programs, and support a health IT environment that rewards innovation and user-centered technology.

18. In March, your agency will release guidance for a new MIPS program. What impact do you expect this will have on MU? What other impacts are you anticipating as a result of MIPS?

Answer: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), through the Merit-based Incentive Payment System (MIPS), considers quality, resource use, clinical practice improvement activities, and meaningful use of health IT in calculating how Medicare physician and practitioner payments are determined. While MACRA continues to require that Medicare physicians and practitioners be measured on their meaningful use of certified EHR technology for purposes of determining their Medicare payments, it provides new flexibility to determine how to measure that use. .

CMS is working closely with provider groups, the consumer community and other important stakeholders to ensure we release an effective proposed rule this spring. The law requires that we continue to measure the meaningful use of ONC Certified EHR Technology under the existing set of standards. While MACRA provides an opportunity to adjust payment incentives associated with EHR incentives, it does not eliminate meaningful use. In addition, the MIPS only addresses Medicare physician and practitioner payments; the EHR incentive programs for Medicare hospitals and Medicaid have a different set of statutory requirements.

The process is ongoing, and we are committed to learning and improving and collaborating on the best solutions. Ultimately, we believe this is a process that will be most successful when physicians and innovators can work together directly to create the best tools to care for patients. We look forward to working collaboratively with stakeholders, including Congress, on advancing MACRA implementation and working to ensure this change is successful in the months ahead.

<u>The Viability of the Health Care Exchanges</u>:

19. On November 19 of last year, United Healthcare, one of the country's largest insurers, reported that it was scaling back advertising of individual plans for this year due to a reduction in expected earnings of $425 million. The company also reported that it saw no reason to expect an improvement in the current climate and that it was considering not offering an exchange plan in 2017. Another large national insurer, Aetna, has made similar undertones. A third large national insurer, Humana, is also terminating several of the large

health plans it offers on the exchanges. Secretary, what do these announcements suggest about the viability of the healthcare exchanges?

Answer: The Marketplace is strong and growing. During the third Marketplace Open Enrollment nine out of ten returning customers were able to choose from three or more issuers for 2016 coverage, up from seven in ten in 2014. During this same period, 12.7 million Americans selected affordable, quality health plans for 2016 coverage through the Marketplaces. In fact, this year 60 percent of our new enrollees signed up in time to have coverage by January 1 , compared to about 40 percent of new enrollees last year.

Health plans are learning how to price and how to offer competitive products that consumers want. We also know that the Marketplace created one of the largest pools of new customers for insurance companies in years. Even as the market meets today's needs and signs millions of new consumers up in record numbers, we also pay attention to adjustments that are needed as the Marketplace matures— whether that's creating new decision support tools for consumers, or strengthening risk adjustment, or clarifying the rules of the road on Special Enrollment Periods. We have full confidence that the Marketplaces will continue to thrive for years ahead.

Insolvency of the Medicare Hospital Insurance Trust Fund:

20. Last year, Medicare's trustees projected the date of exhaustion for the Medicare hospital insurance trust fund at 2030. CBO has accelerated that date by 4 years – to 2026 which is within the budget window. This is so even though the large Medicare spending cuts included in Obamacare – allegedly used to offset the huge costs of that new entitlement – were also supposed to extend the life of Medicare. Given this imminent date of 2026, what are you doing to ensure the long-term viability of the Medicare program?

Answer: The FY 2017 Budget includes a package of Medicare legislative proposals that will save a net $419 billion over 10 years by supporting delivery system reform to promote high-quality, efficient care, improving beneficiary access to care, addressing the rising cost of pharmaceuticals, more closely aligning payments with costs of care, and making structural changes that will reduce federal subsidies to high-income beneficiaries and create incentives for beneficiaries to seek high-value services. These proposals, combined with tax proposals included in the FY 2017 President's Budget, would help extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years.

Competitive Bidding:

21. The current competitive bidding system is failing patients, why do you think further expansion of a broken program is a good idea?

Answer: The Durable Medicare Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program is an essential tool to help Medicare set appropriate payment rates for DMEPOS items by replacing the existing, outdated, excessive fee schedule amounts with market-based prices. The program has resulted in reducing beneficiary out-of-pocket costs, providing significant savings to the Medicare program and taxpayers, and reducing over-utilization and fraud. It has also achieved

billions in savings for Medicare and beneficiaries. Additionally the program has ensured continued beneficiary access to high quality items and services without compromising beneficiary health and safety.

22. **Starting on January 1, 2016, CMS has significantly reduced reimbursement rates for DME items in non-competitive bid areas. Secretary Burwell, can you give me specific details (other than using claims data) how you are monitoring the impact that these cuts are having on patient access to DME items in non-competitive bid areas?**
23. **If you determine that there are access problems with DME items in non-competitive bid areas because of the recent cuts, how you will remedy these problems and how long the process will take? Can you stop the second cut due to take effect on July 1, 2016?**

Answer to 22-23: CMS has been using a real-time claims analysis to monitor health status results in the DME competitive bidding program and other Medicare payment systems. The analysis for the DME competitive bidding program includes key indicators of the health status of beneficiaries and their access to DMEPOS items and services such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. We also monitor beneficiaries who no longer have claims for a competitively bid item after the program began, beneficiaries who may at some point need the item, and beneficiaries who currently have claims for competitively bid items. CMS is doing a similar type of analysis and monitoring for the adjusted DME fee schedule rates during the 6-month transition period and after this transition period. In addition, CMS will be monitoring assignment rates of suppliers. Assignment means that the suppliers have agreed to accept Medicare allowed rate as full payment for the DME item. If there are any issues identified through our monitoring, we will take appropriate actions depending on the situation.

<u>Local Coverage Determinations (LCDs)</u>

24. **Can you explain the agency's views on the recent increase of LCDs that are being adopted across the country on a national scale, and what your agency is doing to ensure that Medicare coverage for precision medicine appropriately fosters innovation and patient care?**

Answer: Local coverage determinations (LCDs) are authorized by statute to allow the Medicare Administrative Contractors (MACs) flexibility in creating innovative and effective coverage policies to meet the needs of beneficiaries in their regions. The LCD process may also provide more expeditious coverage for new technology than may be available at the national level. In creating local policies, the MACs must follow the LCD development process established by CMS, including opportunities for public comment and input from the local medical community through a Contractor Advisory Committee (CAC). In some cases, the MACs may draw upon specialized expertise available at another MAC or may work together to develop more consistent policies. However, if a MAC proposes to adopt a draft policy developed by another MAC, it must still follow all

the required procedural steps, including solicitation of public comments and presentation to the CAC, within its own jurisdiction. More information on the LCD process is available in Chapter 13 of the Medicare Program Integrity Manual at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

The promise of precision medicine is delivering the right treatments, at the right time, to the right person. It is through this promise that we are given one of the greatest opportunities for new medical breakthroughs that we have ever seen. Payment decisions for individuals' care will come under the same processes as all items and services coverable under Medicare Fee for Service. These include coverage by claim by claim adjudication, local coverage determination or national coverage determination. For drug coverage under Part D, plan sponsors' formularies must include adequate coverage of the types of drugs most commonly needed by Part D enrollees, all new drugs must be reviewed by the plan for inclusion on the formulary, and sponsors must have procedures in place that ensure enrollees have access to Part D drugs that are not included on its formulary.

Questions from Representative Jenkins:

Madame Secretary, as I discussed during the hearing, one particular provision of Obamacare that is especially cumbersome and drives up health care costs for everyday Americans is the requirement that individuals have a prescription from a physician in order to purchase over-the-counter medicine with their health savings accounts and flexible spending accounts. I have worked on bill H.R. 1270 – the Restoring Access to Medication Act –which would eliminate this unnecessary requirement that is confusing and a waste of time for patients and physicians. I have worked closely on this legislation for over three years with my colleague, Representative Ron Kind from Wisconsin. When you testified in front of this committee last June, I asked if you would support this type of legislation. At the time you indicated you were not familiar with the issue.

1. **After having time to review H.R. 1270, would you support this bi-partisan legislation?**

Answer: Thank you for raising this issue. As I have said before, we are willing to work with Congress on any proposal that improves access, affordability, quality, and health of the economy. This proposal could have substantial revenue effects and does not meet this test without including an offset. I would defer you to my colleagues at the Department of Treasury for specifics around their regulations.

2. **In addition, the Program of All-Inclusive Care for the Elderly (or PACE) has a proven track record of providing the highest quality of care to some of our most vulnerable seniors - those who need a nursing home level of care but wish to continue living in the community. However, the program only serves**

35,000 people and PACE organizations say they could serve many more. What is the administration doing to build on this successful program?

Answer I share your support for the PACE program, and CMS is taking steps to modernize and streamline PACE enrollment and services.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services. In addition to updating PACE regulations, we are working to implement the PACE Innovation Act of 2015, which expanded the department's authority to allow waivers in order to conduct demonstration projects that involve PACE. CMS is actively working with stakeholder and advocacy groups to determine how the PACE comprehensive care approach can be combined with community care models and expanded to reach a broader population. We will keep your staff apprised of the status of the pilot.

3. **Currently Medicare beneficiaries who enroll in the Program of All-Inclusive Care for the Elderly (or PACE) do not have the option to keep the Part D plan of their choice. For many, this is a disincentive to enroll in PACE. What steps would CMS require to allow Medicare beneficiaries to have a choice in the Part D plan they enroll in if they choose to enroll in PACE?**

Answer: Beneficiaries who join a PACE program get Part D-covered drugs and all other necessary medication from the PACE program. Similarly, in most cases, beneficiaries who choose to join a Medicare Advantage Plan that includes prescription drug coverage must take the drug coverage that comes with the Medicare health plan if it's offered. While we believe coordination between medical and drug benefits under the current system is beneficial, we would be happy to provide technical assistance on any proposals you may have in this area.

Questions for Representative Black of Tennessee:

Last September, the Chairman and members of the Ways and Means Committee sent a letter to CMS asking for critical information on the oversight of the CO-OP program. In their response, CMS states that the agency took assertive actions towards the failing CO-OPs, including placing many on Corrective Action Plans or Enhanced Oversight Plans.

1. **Can you tell me whether CMS required New York to submit to them a corrective action plan?**

CMS provided the Committee with the letters they sent to specific CO-OPs asking for corrective actions, but the Health Republic Insurance of New York was not sent a letter.

2. **It seems unbelievable CMS would overlook the largest CO-OP, covering by far the most enrollees, in their corrective action plans. How was it that this was missed?**

Answer: No. CMS did not issue a corrective action plan to New York prior to the decision to wind down the CO-OP. However, CMS regularly uses enhanced oversight plans (EOPs) and corrective action plans (CAPs) as part of our CO-OP monitoring and oversight process, as laid out in the CO-OP loan agreements and recommended by the HHS OIG. CMS places a CO-OP on an EOP or CAP when it identifies an issue that can be resolved through corrective action.

CMS ordered an independent audit of Health Republic in summer 2015 based on early warning signs about the CO-OP's finances. This independent auditor found higher losses than the CO-OP had expected or projected in its financial reporting to CMS. In this case, the financial problems confronting Health Republic appeared to be too severe to address or correct through a CAP. In the interests of consumers and taxpayers, CMS worked with the State Department of Financial Services, which is the primary insurance regulator, to wind down the CO-OP and to ensure that consumers would have coverage through the end of the year.

3. **How did CMS prioritize their oversight actions for various CO-OP's, if, evidently, this was prioritized not by size, scope, or cost?**

Answer: CMS is committed operating as a proper steward of the taxpayer dollars issued through the loan program and to administering the CO-OP Program for the benefit of consumers. Since awarding both start-up and solvency loans, CMS has been closely monitoring and evaluating the CO-OPs to assess performance and compliance, and has engaged regularly with state DOIs, which are the primary regulators of insurance issuers in the states.

All CO-OPs are subject to standardized, ongoing reporting to and interactions with CMS that include weekly, biweekly, or monthly calls to monitor goals and challenges; periodic on-site visits; performance and financial auditing; and monthly, quarterly, semi-annual,

and annual reporting obligations. Since March 2015, CMS has conducted site visits of CO-OPs in 15 states. We believe these visits are a benefit to plans, consumers, and taxpayers. These visits provide CMS with an opportunity to verify whether and how a CO-OP meets its obligations. During these visits, CMS reviews management structure and staffing, financial status, business strategy, the policies and procedures of the CO-OP, marketing and sales information, and operations, including vendor management and oversight. CMS also reviews whether a CO-OP is meeting their obligations for medical management and member relations. CMS also collaborates with DOIs concerning each CO-OP loan recipient.

CMS prioritizes its oversight efforts based primarily on the financial reporting and regulatory reporting it receives from the CO-OPs on an ongoing basis. CMS monitors the CO-OPs' overall financial condition using several factors of the Federal Deposit Insurance Corporation's Uniform Financial Institutions Rating System. CO-OPs have monthly, semi-annual, and annual reporting requirements, including financial statements, balance sheets, income statements, statements of cash flow, and enrollment statistics. Last year, CMS increased the data and financial reporting requirements for CO-OPs. Each CO-OP is required to provide a semi-annual statement of its compliance with all relevant State licensure requirements, and, if necessary, an explanation of any deficiencies, warnings, additional oversight, or any other adverse action or determination by DOIs received by the CO-OP. If the CO-OP is experiencing compliance issues with State regulators, the CO-OP is required to describe the steps being taken to resolve those issues. CMS meets monthly with the state insurance regulators regarding each CO-OP. This additional financial data collection has helped CMS to identify underperforming CO-OPs and gives CMS the opportunity to work with the CO-OPs and DOIs to help correct issues that are identified.

4. **Are you similarly looking into whether Health Republic misrepresented their finances to you?**

Answer: As a normal course of action, in any of the situations where a CO-OP is no longer operating, CMS is conducting financial reviews and audits to ensure that funds were spent appropriately. After a CO-OP has been placed in receivership, CMS is limited in its ability as a creditor to control or investigate a CO-OP that has gone into supervised liquidation under state law. However as called for in statute, once a CO-OP loan agreement (like other Federal loans) is terminated, the loans become due as present debts, and CMS is obligated by statute to refer those debts to the Civil Division of the Department of Justice for collection.

The changes necessary to implement Section 2 of the Patient Access and Medicare Protection Act could be accomplished through the use of a billing modifier and a fee schedule update. In the past, CMS has used this method to address situations similar to the one we are discussing today. Further, modifiers and fee schedules are routinely updated as need.

5. **Keeping that in mind, I am having difficulty understanding why CMS is insisting that the law requires a non-routine update that cannot be implemented until July?**

6. **What sort of advanced planning is usually necessary for CMS to implement these types of changes in its system? I would like to know how often CMS updates its fee schedules for products and services, on average, each year.**

Answer: We are aware of and appreciate your concerns regarding this issue. CMS began working on implementation of the Patient Access and Medicare Protection Act of 2015 (PAMPA) when it first passed Congress in late December. Since PAMPA was signed into law at the end of December, it would not have been feasible for CMS to implement it on January 1, 2016. Given the amount of system changes required and the testing involved, the soonest they are able to implement this change is July 1, 2016. Until these changes are implemented, payments for these items will be based on the adjusted DME fee schedule amounts. The DME adjusted fee schedule rates are currently in a 50/50 blend during this 6 month transition period. The average reductions for these Group 3 complex rehabilitative wheelchair accessories are about 10 percent. On or after July 1, 2016, suppliers will receive the full fee schedule amount.

To ensure beneficiary access to these accessories particularly for these vulnerable populations, advance payment may be available for suppliers. According to our regulations, an advance payment means a conditional partial payment made by the contractor in response to a claim that is unable to process within established time limits. Suppliers are able to submit a single advance payment request to their Medicare Administrative Contractor for multiple claims during this period. These advance payments may be issued if certain regulatory requirements are met.

CMS will be monitoring beneficiary access closely during this time to ensure they receive the wheelchairs and accessories that they need.

In Medicare, Medicaid and the private sector, health care delivery and payment systems are seeing significant and accelerating change. Yet the Program of All-Inclusive Care for the Elderly (or PACE), which pioneered so many of the features we now seek to build into our health care system, is being constrained by regulations that are almost a decade old.

7. **What is the administration doing to update these regulations and provide more flexibility to PACE so that our seniors can have greater access to its gold-standard, proven and replicable model of integrated, community-based and person-centered care?**

Answer: I share your support for the PACE program, and CMS is taking steps to modernize and streamline PACE enrollment and services.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services.

I am concerned that recent news indicates too much instability in the individual market. Although you are highlighting a 90 percent coverage rate, enrollment expansions in the individual market are far below initial projections. Consumers who are willing to do their part by paying a full year of premiums are paying higher rates because the exchanges allow people to sign up for "just-in-time" medical services during what are designated as "special enrollment periods (SEPs)."

I've heard you talk about the "strength of the marketplace" but I also hear about the millions of dollars in issuer losses coming in a significant proportion from these SEPs, and I'm concerned about the long-term sustainability of the market. I recognize your agency recently announced the elimination of 7 SEPs, but my understanding is that three of them were already expired, and the other four do not address the problem in a significant manner. I also find it ironic that days later your agency announced a brand new SEP for delinquent tax filers.

I am also concerned about the ever moving and expanding open enrollment (OE) period. The original ACA regulations had OE periods that ended in early December. Allowing individuals to continue to enroll after the current policy year can encourage anti-selection and letting purchasers pay for only a partial year of coverage, while still receiving a full year of coverage.

8. **Does HHS plan to significantly eliminate more SEPs in the near future, and will there be any attempt to enforce or attest the existing ones?**

Answer: Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- clarifying language to make the rules of the road are clear to everyone,
- reviewing all SEPs and eliminating those that are no longer necessary, such as:
    - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy
    - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
    - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
    - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
    - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
    - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program.

We have also provided stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes. For example, we will conduct an assessment of plan selections that are made through certain special enrollment periods to evaluate whether consumers properly accessed coverage.

Our program integrity team will pull samples of consumer records nationally and may request additional information from some consumers or take other steps to validate that consumers properly qualified for these special enrollment periods. The findings from the assessment will help us to inform future policy and operational improvements to enhance program integrity. We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.

9. Does HHS plan to limit or expand the open enrollment period?

Answer: As you may know, each year CMS releases a Proposed Notice of Benefit and Payment Parameters, in which we detail certain proposed policies for the upcoming plan year. In the 2017 payment notice, CMS proposed dates for the individual market annual open enrollment period for the 2017 benefit year. For 2017, we proposed to maintain the same open enrollment period we adopted for 2016—that is, November 1, 2016, through January 31, 2017. The rule also noted that we are considering defining the open enrollment period for coverage year 2018, and sought comment on what that period should be.

10. The Healthcare.gov website has a tab front-and-center that asks users to see if they can get coverage outside the open enrollment period. Do you keep track of who is getting coverage through SEPs and exactly for what reasons, such as giving birth, moving, etc., or are they just all lumped together?

11. **If they are lumped together, why can't you keep track of what SEPs are being used, in order to ensure federal dollars are being spent appropriately?**

12. **If you are not able to keep track of SEPs, how will you carry out back end enforcement?**

Answer: Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

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    - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
    - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
    - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
    - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
    - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and
- providing stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes.

We have also provided stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes. For example, we will conduct an assessment of plan selections that are made through certain special enrollment periods to evaluate whether consumers properly accessed coverage.

Our program integrity team will pull samples of consumer records nationally and may request additional information from some consumers or take other steps to validate that consumers properly qualified for these special enrollment periods. The findings from the assessment will help us to inform future policy and operational improvements to enhance program integrity.

We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future

13. Does HHS plan to limit or expand the open enrollment period?

Please see response to Question 9.

Questions from Representative Kelly of Pennsylvania:

Despite support from both parties and from the Administration for Quality Incentive Payments in Medicare Advantage, those payments have been reduced or eliminated for many 4 and 5-star plans because of the ACA MA benchmark cap. Madame Secretary, I recently introduced legislation - HR 4275, along with my colleagues Ron Kind, Mike Doyle and Brett Guthrie - that would solve this problem.

1. **But we believe that HHS has the authority to make the change WITHOUT legislation. A strict reading of the law undermines the intent of the ACA to pay for value in Medicare Advantage. Will you ask your lawyers if they can re-examine their interpretation to find a way that you can exclude the quality payments from the calculation of the cap?**

Answer: We appreciate your interest in this area and your support of the Agency's efforts to pay for value. We do not believe we have the discretion to eliminate application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation. The bonus payment is based on an increase to the 'applicable percentage' which is a component of the benchmark calculation itself.

The Budget includes a proposal to reform Medicare Advantage payments to improve the efficiency and achieve sustainability of the program for all Medicare beneficiaries. This proposal has four components that better incentivize Medicare Advantage plans to submit cost-effective bids while preserving beneficiary supplemental benefits and enhancing quality incentives. As part of the balanced and comprehensive approach, the proposal would standardize quality bonus payments across counties by removing the doubling of the quality bonus payment which is only available in certain areas and lifting the cap on benchmarks for plans that are entitled to receive a quality bonus payment. I look forward to working with the subcommittee to enact reforms to Medicare Advantage payments.

Questions from Representative Smith of Nebraska:

As you know, I continue to be concerned about the solvency of the remaining Consumer Oriented and Operated Plans (s), and whether the taxpayer dollars loaned to the CO-OPs will ever be repaid.

In a January 6, 2016, letter, CMS Acting Administrator Andrew M. Slavitt stated "CMS will use every available tool to recoup loan funding" from CO-OPs which are wound down. Please provide an update on recovery of funds from CO-OPs which have been or are being wound down.

1. **Has HHS or CMS estimated how much money will be recovered from the failed CO-OPs? If so, what is that estimate and how was it calculated?**

Answer: CMS takes our obligation to taxpayers very seriously. While it is too early to tell how much money can be recovered, CMS will take aggressive steps to recover all the money we can. Providers can still submit claims after the date of a service, meaning that it will take time to develop a full picture of a CO-OP's finances. Collection efforts will be dictated by the terms of the loan agreement, and state and federal laws. We have begun the formal process of recovering funds by terminating loans for many CO-OPs and notifying them of their obligation to repay the loans. We are working in close collaboration with the US Department of Justice and will use all available tools to recover loan funds owed by these companies.

2. **What is the financial status of the remaining CO-OPs? Do you expect additional CO-OPs to suspend operations in 2016? If so, how many?**

Answer: CMS is closely monitoring the eleven remaining CO-OPs. Each of these CO-OPs were approved by their State Department of Insurance to offer coverage for the 2016 plan year. We will continue to work closely with the Departments of Insurance to protect consumers and taxpayers.

3. **Do you project the remaining CO-OPs will repay their loans on time, under the terms of their contracts with CMS? What is the basis for that determination?**

Answer: As you know, the CO-OP loans are not due to be repaid until 5 to fifteen years after the date funds are disbursed under the loan. We will continue to work with the remaining CO-Ops so that they are best positioned to fulfill their obligations under the terms of the loan agreements.

Questions from Representative Kind of Wisconsin:

I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk consumed by young children. My understanding is this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the US dairy industry that need to be further examined.

1. **Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?**

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,[9] and presented it to the WHO Executive Board (EB) for potential

[9] As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf (Accessed March 14, 2016).

endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

Questions from Representative Rangel of New York:

Madame Secretary – I want to ask you a question about third-party premium assistance programs that are operated by non-profits. Some of these programs have existed prior to the passage of the Affordable Care Act and many for decades.

Since CMS released an Interim Final Rule in March 2014, raising the issue of third-party payment of health insurance premiums, a growing number of insurance carriers are refusing to accept third party payments from non-profit organizations. These non-profit organizations have a long and proven track record of helping people with chronic conditions maintain affordable health coverage. I understand that there are certain statutory provisions related to premium assistance provided through the Ryan White Care Act and for our tribes.

1. **Can you explain why HHS does not require insurance companies to accept third-party payments from non-profits on behalf of insured people with chronic conditions? Is there anything in the statute that bars you from doing so? Isn't it appropriate to consider applying the same protections to people battling kidney disease as those you've applied to people with HIV? Do you**

agree that both groups should be protected from discriminatory insurance practices?

Answer: Thank you for raising this important issue. In the Interim Final Rule, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because federal or state law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

For example, section 402 of the Indian Health Care Improvement Act and the relevant regulations, which implement the Affordable Care Act, provide that Marketplaces may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Marketplace.

In addition, the Ryan White HIV/AIDS Program has been authorized to provide insurance assistance for low-income people living with HIV since 1990 under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. States have the authority to use AIDS Drug Assistance Program grant funds to purchase or maintain health insurance or plans when the coverage includes the relevant therapeutics and the cost of such coverage does not exceed the costs of otherwise providing the therapeutics directly. This provision was added in 2000 by the Ryan White CARE Act Amendments of 2000.

As noted in the November 4, 2013 FAQ, it has been suggested that hospitals, other health care providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an uneven field in the Marketplaces.

Issuers may still choose to accept third party payments from non-profits, and in an FAQ published in February 2014,[10] CMS noted that it does not believe this creates adverse risk selection so long as the criteria for premium assistance is based on financial need, not health status, and that the assistance continues through the entire plan year.

I would like to paint a picture for you of the type of people charitable premium-assistance organizations are trying to help. These are people with very significant health care needs, but very little in terms of financial resources. For example, the American Kidney Fund (AKF) provides charitable assistance to disabled individuals who are on dialysis. These patients tend to be older – 48 percent are older than 60. They're also disproportionately minority when compared to the U.S. population; 38 percent of AKF grant recipients are African American and 15 percent are of Hispanic ethnicity. Fully 70 percent of the patients AKF helps are unemployed, while another 20 percent work only part-time. To qualify for assistance from AKF

[10] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf

for health insurance premiums, patients must have extremely low-income relative to expenses. Sixty percent of the patients AKF assists have annual household incomes under $20,000. At the same time, they have average annual out-of-pocket medical expenses of close to $7,000.

This is an economically and physically fragile population. When insurers refuse third-party payments from a non-profit like the AKF, this jeopardizes patients' access to appropriate coverage.

In my congressional district, I have around 100 patients who received assistance from AKF. And across the state of New York, we have over 2000 patients who have received assistance in 2015.

1. **Do you think that insurers may be engaging in discriminatory practices? One of the goals of the ACA was to prohibit discrimination against people with pre-existing conditions? Do you agree this policy undermines that goal and encourages discriminatory practices by insurers to occur?**

Answer: The Affordable Care Act reformed the health insurance marketplace to ensure that individuals with pre-existing conditions are able to access care by prohibiting insurance plans from discriminating against consumers with pre-existing conditions or charging them more because they got sick or lifetime limits on their insurance. In addition, with respect to the Marketplace specifically, the ACA provides for both tax credits to help consumers afford their premiums, and reduced cost- sharing for consumers who qualify. These market reforms and financial assistance work together to ensure access to care.

As noted in the HHS Notice of Benefit and Payment Parameters for 2017 proposed rule, HHS is considering whether to expand the list of entities from which issuers are required to accept payment to include not-for-profit charitable organizations in future years. If such not-for-profit charitable organizations were included, HHS would also intend to include guardrails aimed at minimizing the impact on the risk pool, such as limiting assistance to individuals not eligible for other Minimum Essential Coverage and requiring assistance until the end of the calendar year.

Question from Representative Davis Illinois:

Madame Secretary - I want to ask you a question about third-party premium assistance programs that are operated by non-profits. Some of these programs have existed prior to the passage of the Affordable Care Act and many for decades.

Since CMS released an Interim Final Rule in March 2014, raising the issue of third-party payment of health insurance premiums, a growing number of insurance carriers are refusing to accept third party payments from non-profit organizations. These non-profit organizations have a long and proven track record of helping people with chronic conditions maintain affordable health coverage. I understand

that there are certain statutory provisions related to premium assistance provided through the Ryan White Care Act and for our tribes.

1. **Can you explain why HHS does not require insurance companies to accept third-party payments from non-profits on behalf of insured people with chronic conditions? Is there anything in the statute that bars you from doing so?**

Answer: In the Interim Final Rule, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because federal or state law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

As noted in the November 4, 2013 FAQ, it has been suggested that hospitals, other health care providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an uneven field in the Marketplaces.

CMS later clarified that the concerns addressed in the November 4, 2013 FAQ would not apply to payments from private, not-for-profit foundations if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. CMS noted that it does not believe this creates adverse risk selection so long as the criteria for premium assistance is based on financial need, not health status, and that the assistance continues through the entire plan year.

Questions from Representative Pascrell of New Jersey:

In your response to my question about how HHS will work to support incorporating UDI into health insurance claims, you stated that there are external boards that provide recommendations on changes and additions to the claims form. However, as you know, those organizations take guidance from health plans, including Medicare, and CMS plays a substantial role in developing those recommendations. The decision to incorporate UDI into the claims form has implications for other agencies within HHS. FDA has repeatedly expressed support for UDI in claims to bolster its ability to conduct post-market surveillance of medical devices. The major problem with duodenoscopes shed light on a number of deficiencies in the current post-market surveillance system and highlighted the need to provide FDA with additional tools to perform this essential agency function.

1. **As the head of the department that oversees both of those agencies, how do you plan to ensure that CMS' participation in that process adequately accounts for implications for other agencies, particularly FDA?**

Answer: We share the important goal of improving patient safety through post-market

surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC's approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, having UDIs incorporated into EHRs will allow the use of a device to be linked with a patient's experience with that device, thereby generating better information for patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

2. **The Centers for Medicare and Medicaid Services (CMS) has made investments totaling more than $2 billion to pilot new delivery and payment system models. While many of these are promising, further experience and evaluation will be needed to know what works and what can be replicated. At the same time, CMS can build on existing models that have already stood the test of time, including the Program of All-Inclusive Care for the Elderly. How is CMS balancing its investment in new models with its investment in expanding existing, proven models?**

Answer: I share your support for the PACE program, and agree that is it important to build on successful existing models as we test other delivery system reforms.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services.

At the same time, the Innovation Center looks forward to building on its existing work while testing new models. The Secretary has the authority to expand the duration and scope of a model through rulemaking if certain statutory criteria are met: (1) an expansion is expected to reduce spending without reducing the quality of care, or improve the quality of care without increasing spending (2) the CMS Chief Actuary certifies that an expansion would reduce (or would not result in an increase in) net program spending and (3) an expansion is expected to not deny or limit coverage or benefits. The Innovation Center conducts an independent evaluation of each payment and service delivery model tested. Using these evaluation results, as well as other available data, the Innovation Center makes decisions regarding expansions in accordance with the statutory requirements and each model's unique elements.

The Innovation Center is also committed to developing and testing new models. New models are developed in accordance with the Innovation Center's purpose to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, or Children's Health Insurance Program (CHIP) beneficiaries. Moreover, in accordance with section 1115A(b), models to be tested under section 1115A must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. During the development of models, the Innovation Center builds on ideas received from stakeholders and consults with clinical and analytical experts, as well as with representatives of relevant federal and state agencies. Through these efforts, the Innovation Center balances investment in expanding existing models and testing new initiatives.

3. **CMS is long overdue in finalizing regulations to adopt a standard claim attachment. Once CMS adopts and implements a standard claims attachment, how does the agency intend to integrate this information into databases that also contain information from claims? Does the agency intend to provide FDA, researchers, innovators and registries with access to claims attachment data in the same manner that the agency has provided access to claims data? If so, how, and if not, why not?**

Answer: The Secretary is required to promulgate a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments. In 2005, HHS issued a proposed rule which would have established both transaction and content standards for claims attachments. Due to stakeholder comments, that rule was never finalized. HHS is closely tracking the work of the standard setting organizations on the development of claims attachment standards. In fact, in February 2016, the National Committee of Vital Statistics (NCVHS) has scheduled hearings from stakeholders on claims attachments. CMS looks forward to future recommendations from NCVHS on this topic.

4. **Section 2 of the Autism Collaboration, Accountability, Research, Education, and Support Act of 2014 (Public Law 113-157) requires the Secretary of HHS to designate an official to oversee national autism spectrum disorder research, services, and support activities. It also directs the official to**

implement such activities taking into account the strategic plan developed by the Interagency Autism Coordinating Committee and ensure that duplication of activities by federal agencies is minimized. What is the status of the designee?

Answer: The Department looks forward to announcing this spring a designee to (1) oversee national autism spectrum disorder research, services, and support activities, (2) implement autism spectrum disorder activities, taking into account the strategic plan developed by the Interagency Autism Coordinating Committee and (3) ensure that autism spectrum disorder activities of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative. In addition to their existing duties, this designee will serve as Autism Coordinator for the Department. We expect this appointment in the near-term, and will keep your office appraised.

5. **A number of hospitals in my state of New Jersey have expressed concerns about the change to the Hospital outpatient reimbursement included in the Bipartisan Budget Act of 2015 (Public Law 114-74). Can you please clarify whether the Hospital Outpatient Departments that are currently grandfathered will be able to relocate and add services without losing their status as a Hospital Outpatient Department?**

6. **New Jersey Hospitals have asked that the regulatory guidance on the Hospital outpatient reimbursement policy included in the Bipartisan Budget Act of 2015 (Public Law 114-74) be issued as soon as possible. Would CMS be willing to issue proposed regulations on this policy before it issues the Outpatient Prospective Payment Rule, such as part of the Inpatient Prospective Payment proposed regulation to be issued in the Spring session of 2016?**

Answer: CMS has posted publicly that this provision will be addressed through rulemaking in the CY 2017 Hospital Outpatient Prospective Payment System (OPPS) proposed rule which is generally issued in the summer. Here is the link to the notice: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Note-Regarding-Implementation-of-Section-603-of-the-Bipartisan-Budget-Act-of-2015.pdf.

If there is a scenario regarding implementation of Section 603 that you are concerned about and want to call attention to it for the proposed rule, CMS would be happy to review any comments you would like to submit. In addition, the public will have the opportunity to comment on the proposed rule per the standard notice and comment rulemaking process. Additionally, please feel free to reach out to Jim Esquea on my staff to discuss any specifics.

7. **CMS has launched unprecedented new initiatives to release Medicare claims data on procedures, medications and some medical supplies. CMS last year even expanded access to Medicare claims data to researchers and manufacturers of medical products. And, just last month, CMS issued regulations that will enhance the use and availability of Medicare data in implementing legislation that was championed in a bipartisan way and advanced by the former chairman of this committee, who now also happens to be the Speaker of the House. In implementing all these policies, CMS has described claims data as an "essential ingredient to building a better, smarter, healthier system" that would help "make smarter and more informed healthcare decisions". The most common Medicare hospital procedure involves hip and knee implantation procedures, affecting 400,000 seniors per year and accounting for $7 billion in spending. And that doesn't even count the millions of patients with cardiac stents and other implanted devices. Adding the unique device identifier to claims data would ensure that this information can be just as valuable for implants as they are for drugs and other medical interventions. Given that CMS believes that Medicare claims data are critically important to improve patient care and reduce costs, why is it different for medical implants used in the most common Medicare procedures? Why does CMS believe claims data are essential to our learning healthcare system, just not for medical implants?**

Answer: Congressman, we share the important goal of improving patient safety through post-market surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC's approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, having UDIs incorporated into EHRs will allow the use of a device to be linked with a patient's experience with that device, thereby generating better information for patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

Questions from Representative Crowley of New York:

For over 10 years, HRSA has been overseeing a process at UNOS to revise the organ donation system so that it is more needs-based rather than solely geographic-based. As this process has continued, stakeholders in New York State and other states impacted by the current process are eagerly awaiting resolution, as are the many patients who remain on the organ transplant wait list.

1. **Can you provide information about the timeline for a decision and an update on what progress HRSA and UNOS are making with these deliberations?**

Answer: Any change in the OPTN liver allocation policy must be consistent with the requirements and principles of the OPTN final rule, which articulates the goals to be achieved through OPTN organ allocation policies. These policies must, among other factors, be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements).

Consistent with OPTN processes and requirements for the development of changes to the liver allocation policy, several key activities and policy changes have been completed in the last several years. Since 2014, the following steps have been taken to inform discussions of potential changes to the liver allocation policy regarding geographic challenges and alternative approaches to liver allocation.

HRSA anticipates that the Liver Committee will publish on the OPTN web site a policy proposal for public comment (60-day comment period) by January 2017, then subsequently review the feedback. Next, the OPTN Board will vote on a policy proposal.

Questions from Ways and Means Committee:

1. **Does the Administration plan to use physician developed AUC in the ordering of advanced imaging studies instead of the ongoing prior-authorization policies? Please explain to the Committee why the Agency will not meet the implementation deadline of January 2017 and please tell the Committee a date certain as to when this program will be implemented.**

Answer: CMS is required to adhere to rapid timelines for establishing a new Medicare Appropriate Use Criteria (AUC) program for advanced imaging services. The number of clinicians impacted by the scope of this program is significant as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. It is for these reasons we proposed a stepwise approach,

adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

2. **In order to improve patient outcomes and enhance quality of care, the new formula by which Medicare will reimburse physicians will incorporate patient engagement features. As structured, the beneficiary engagement subcategory within the Merit-Based Incentive Payment System (MIPS) references beneficiary self-management training and recognizes that to achieve successful beneficiary self-management training, the patient¹s self-management capabilities must first be assessed. The tool providers use to assess patient self-management capability makes a difference.**

3. **As CMS develops MIPS, will it direct providers to rely on an empirically validated, interval level, patient self-management assessment tool to determine a beneficiary¹s self-management capabilities? The use of measures that are validated and proven reliable through extensive peer-reviewed studies, national and international usage and that have empirically validated interval level measurement have proven capabilities to be acted upon - through intervention by patients and providers - in order to improve self-management and reduce unwarranted utilization.**

Answer to 2-3: As laid out in statute, the Merit-based Incentive Payment System (MIPS) is a rigorous value-based purchasing program for physician and practitioner services. EPs will be scored under MIPS based on a single composite performance score, which will factor in performance in four weighted categories: quality, resource use, clinical practice improvement activities, and meaningful use of certified electronic health record technology. We are working hard to establish the proposed measures and activities that will fall under each of the four MIPS categories and appreciate the feedback we have received from stakeholders, particularly regarding areas that are new to CMS, such as clinical practice improvement activities. We are committed to building a program that fulfills the goals of advancing quality and value, while being adaptive to the needs of each clinician's individual practice and patient population. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

4. **What is the status of CMS¹s efforts to stop improper payments before they are made? What impediments exist, if any, for using recovery auditor to execute pre-payment reviews of Medicare payments?**

Answer: CMS' program integrity strategy is moving beyond the reactive "pay and chase" method toward a more effective, proactive strategy that identifies potential improper payments before they are made, keeps unscrupulous providers and suppliers out of Medicare and Medicaid at the outset, quickly removes wrongdoers from the programs

once they are detected, and corrects improper payments as quickly as possible. CMS uses many tools as part of this strategy, such as prior authorization. CMS believes using a prior authorization process will help ensure that all relevant coverage, coding, and payment requirements are met before the service is rendered and the claim is submitted for payment.

CMS also uses prepayment reviews as part of this proactive strategy. CMS' Medicare Administrative Contractors, which process Medicare Part A and Part B medical claims or DMEPOS claims for Medicare Fee-For-Service (FFS) beneficiaries, may conduct prepayment reviews after the service is provided and the claim is submitted for payment but before the claim is paid. CMS continues to focus on prepayment reviews of claims that have historically resulted in high rates of improper payments. This will help stop improper payments before the claims are paid, and as a result, reduce the improper payment rate.

CMS also utilizes a sophisticated predictive analytics technology, called the Fraud Prevention System (FPS), to prevent and detect fraud, waste, and abuse in the Medicare FFS program. The FPS provides a comprehensive view of Medicare FFS provider and beneficiary activities in order to identify and analyze provider networks, billing patterns and beneficiary utilization patterns, and detect patterns that represent a high risk of fraudulent activity. Over the first three years of implementation, FPS identified or prevented $820 million in inappropriate payments.

The statute specifically authorizes CMS to make payment to Recovery Auditors only from amounts recovered. However, in September 2012, CMS allowed Recovery Auditors to review claims before they are paid as part of the Recovery Auditor Prepayment Review Demonstration. The demonstration was conducted in seven states with high incidences of improper payments and fraud, as well as four states with the high numbers of short hospital stays. As part of the close-out process for the existing Recovery Auditor contracts while CMS worked to procure new contractors, the prepayment demonstration was paused and remains on hold while CMS assesses its options regarding the procurement of the next Recovery Auditor contracts.

5. **What is the timeline HHS/CMS expects to adhere to in terms of finalizing the procurement for the next round of Recovery Audit contracts?**

Answer: The current Recovery Auditors are under contract to continue their active recovery auditing work through July 2016 to allow completion of the new procurement process. In November 2015, CMS posted the Request For Proposal (RFP) for the new Medicare Fee-for-Service Recovery Auditor contracts. CMS is actively engaged in the procurement process for the next round of Medicare Fee-for-Service Recovery Auditor contracts.

I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk consumed by young children. My understanding is this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the US dairy

industry that need to be further examined.

6. **Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?**

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,[11] and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

The Office of Civil Rights (OCR) is seeking a $3.6 million increase in funding for fiscal 2017, $1.36 million of which it would use to enforce the ACA's non-discrimination provision, which is expected to increase the OCR's workload by 25 percent as it reviews cases on whether insurers' specialty drug cost-sharing or medical service exclusions are discriminatory. Discriminatory practices related to the disproportionately high cost-sharing required for drugs for the treatment of HIV have been widely reported in the media. However, increasingly there have been reports about such treatment in other chronic diseases, such as rheumatoid arthritis, psoriasis and psoriatic arthritis, multiple sclerosis and even some types of

[11] As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf (Accessed March 14, 2016).

cancer. One way to ensure appropriate access and sufficient patient protections is to have robust oversight prior to plan marketing, so beneficiaries are not forced to the last resort of the office of civil rights.

7. **How does HHS intend to ensure that benefit designs, including the use of high cost sharing tiers, and the utilization management practices like step therapy/fail first protocols are used appropriately and don't inhibit access to medications for chronic diseases for beneficiaries?**

Answer: As detailed in the Draft 2017 Letter to Issuers in Federally-Facilitated Marketplace, non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces for non-grandfathered health insurance plans offered in the individual and small group markets. An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

As part of that guidance CMS cautioned issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, CMS noted that if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those conditions.

The enforcement of this standard is largely conducted by States. CMS has encouraged States that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited, to analysis of information entered in the QHP Plans and Benefits Template.

8. **How will HHS ensure that both plans participating in the Exchanges, as well as plans participating in MA-PD are offering robust formulary access for medications that treat chronic diseases?**

Answer: CMS has policies to promote access to medications for consumers enrolling in coverage through the Marketplace and for Medicare beneficiaries. With regard to the Marketplaces, Qualified Health Plans must offer a range of benefits including benefits in at least ten broad categories, including prescription drugs. As noted in the answer to question # 8 below, as part of the certification process, CMS reviews data submitted by plans to ensure non-discrimination in QHP prescription benefit design.

Part of this review includes reviews for adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

For Medicare, CMS encourages Part D sponsors, including MA-PD sponsors, to submit formularies similar to those in widespread use today. CMS reviews the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary.

A Health Business Daily article, "CMS Might Take Deeper Dive Into Outlier Drug Costs to Find Discriminatory Designs" (June 29, 2015), states, "Although the issue of discriminatory plan design is on the radar of the National Association of State Insurance Commissioners, few, if any, states have the qualitative rigor needed to conduct a sophisticated analysis of benefit designs. Moreover, they generally don't have clinicians, pharmacists or statisticians on staff. Identifying outliers might be easier for states where only a few carriers compete."

9. **What steps are being taken by CCIIO and CMS to analyze the prevalence of these aggressive tactics, including specialty tiers and the frequent use of step therapy/fail first protocols and the potential health outcome impact on patients in the exchanges and Medicare?**

Answer: Thank you for raising this important issue. It is critical that patients are able to access the care they need when they need it and I look forward to working with you broadly on these issues. In addition to the reviews for non-discrimination in EHBs as part of the 2017 QHP Certification process, CMS has proposed to review QHP's formulary drug list to ensure non-discrimination in their prescription benefit design. CMS has proposed to perform an outlier analysis that compares seeking certification to be offered through an FFM and flag those identified as outliers based on both includes both State-level and national lower threshold values. QHPs that are outliers have an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia category and class. CMS requires that QHPs meet or exceed both threshold values. CMS also encourages States performing plan management functions to implement this type of review.

In addition, as we have in prior years, CMS will review each QHP's prescription drug coverage to determine that it meets applicable standards laid out in regulation. Based on data submitted by issuers in the prescription drug template, this review will analyze the availability of drugs recommended by nationally-recognized clinical guidelines used in the treatment of specific medical conditions. The medical conditions included in the

review include the following: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia. In addition to analyzing the appropriate coverage of drugs recommended by the clinical guidelines, the review will also analyze cost-sharing requirements associated with these drugs so that they are not used to dissuade consumers with such conditions from enrolling in the QHP. This portion of the review will identify QHPs that are outliers based on the presence of unusually high cost-sharing requirements for specific drugs. Other additional medical conditions may be considered as part of future reviews.

Finally, CMS will conduct a review of each QHP's coverage of standard treatment protocols for the treatment of certain chronic and high-cost medical conditions which includes the associated medical services and drug coverage for first and second line therapies as recommended by nationally-recognized clinical guidelines. CMS is also concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

With regard to monitoring the use of utilization management tools and specialty tiers in Medicare Part D, as a part of formulary review, CMS will look to existing best practices to check that Part D sponsors' use of prior authorization, step therapy, and quantity limits is consistent with such practices. CMS will look to current industry standards as well as appropriate guidelines that might be found from expert organizations and to the use of such standards in existing drug sponsors that are widely used by seniors and people with disabilities. CMS will ensure that sponsors' use of such tools is consistent with best practices. CMS will also compare formularies among the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. In cases where a sponsor may fall outside of best practices, the sponsor will be asked to provide a reasonable justification for its practices. CMS' expectation is that formulary benefit management tools will be used in Part D formularies consistent with the way they are applied in existing formulary systems.

CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the standard deductible and before the initial coverage limit (or up to 33% for sponsors with decreased or no deductible under alternative prescription drug coverage designs). When applying a reduced deductible, sponsors are limited to the maximum specialty coinsurance levels as defined each year in the Bid User Manual. The deductible applied to the non-specialty tiers may not exceed the deductible that is applied to the specialty tier.
- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty

tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar per-month threshold and are intended for inclusion in the specialty tier.

- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

10. **Moreover, CMS has proposed in the most recent draft Notice of Benefit and Payment Parameters ways to standardized benefit designs. While standardization has some benefits for consumers, some of the agency's of proposed designs would perpetuate the discriminatory nature of what we're seeing in the exchanges. Some states have taken action to address this discrimination through legislation (e.g., Capping monthly out of pocket pharmacy costs); what steps is the agency to support these state efforts and ensure that it doesn't take steps to actually hurt those efforts?**

Answer: Standardized plans would be optional for issuers, meaning health plans would not be required to offer them. However, we believe that standardized options would allow consumers to more easily compare plans offered by different issuers within each metal level and thereby simplify the consumer shopping experience by allowing them to focus their selection on other factors like networks, premiums, and quality. Each of these options is standardized in terms of in-network cost-sharing: deductible, annual limitation on cost-sharing, and copayment or coinsurance for a key set of EHBs that comprise a large percentage of the average enrollee's total spending.

With respect to prescription drugs, we proposed that standardized options have the four drug tiers currently utilized in our consumer-facing applications at this time—generic, preferred brand, non-preferred brand, and specialty drug tiers. However, we proposed to allow issuers to offer additional lower-cost tiers if desired. Slightly more than half (56 percent) of the proposed 2016 FFE QHPs have more than four drug tiers. We believe that standardized options would be a valuable consumer tool that allows consumers to more easily compare plans. However, as noted above, CMS also plans to conduct rigorous review for potentially discriminatory benefit design during the certification process, including specific reviews for prescription drugs.

11. **The Medicare Part D Program has continued to come in under cost estimates, but also has in place important patient protections. For instance, Part D plans are required to provide a 3 month transition supply for beneficiaries who are stable on medication, but have lost formulary access to the medication or are subjected to new fail first policies. No such protections are in place for beneficiaries receiving benefits through the Exchange. Why has HHS not provided protections consistent with those provided to Medicare beneficiaries for enrollees in Exchange plans?**

Answer: The Marketplace and Medicare are different programs with different authorizing statutes.

As you may know, marketplace plans must have processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing.

In addition, as noted earlier, CMS has proposed to review QHPs' formulary drug list to ensure non-discrimination in QHP prescription benefit design. CMS has proposed to perform an outlier analysis where plans are compared to other plans seeking certification to be offered through an FFM and flagged when identified as outliers. The outlier calculation includes both State-level and national lower outlier threshold values. CMS requires that QHPs meet or exceed both threshold values. QHPs that are outliers have an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia (USP) category and class. CMS also encourages States performing plan management functions to implement this type of review.

12. **Non-medical switching is defined as, "when patients that are stable on a medication are switched for non-medical reasons for the purpose of controlling costs to the insurer/payer." As a result of these medication switches, patients may suffer negative side effects and/or may not longer respond to treatment even if returned to their original medication. In fact, patients who are switched may increase utilization costs due to unintended medical consequences of the switch. Data on this type of activity is critical to protect patients and track the cost of switching. How will the agency collect data and monitor this issue on behalf of beneficiaries to ensure NMS does not lead to problems with adherence to medication or changes in utilization costs as a result of the switch?**

13. **Are you aware of any instances where plans have passed on additional costs to patients or forced patients to switch from one medication to another in order to facilitate increased cost-savings? Are the health and safety consequences of this activity well known and/or understood?**

Answer: From the Marketplace perspective, CMS does not have access to or track individual patient data – such data resides with private Marketplace issuers. However, as described in greater detail above, all Marketplace plans must provide essential health benefits (EHB), including prescription drugs. Marketplace regulations contain a prohibition on discrimination and provide that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an

individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

14. Given the recent release and retraction of a proposed Part B drug demo project within CMMI, can you inform us of the status of this project and whether this project will be subject to public review and comment?

Answer: Last fall, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from state and federal government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation while protecting access and affordability. We came away with feedback to address these challenges in a holistic fashion addressing three important areas: (1) increasing access to information to support better health care decisions, (2) driving innovation that improve and save lives, (3) and strengthening incentives in the delivery system to reward quality care to patients and encourage value-based and outcomes-based decision making.

Coming out of that forum, we have identified several areas of potential opportunity for consideration and collaborative policy development. The need for better information about drug prices and impacts on patients and providers in making better health care decisions was one theme that we heard across multiple panels. To that end, in December, we took a first step forward by providing more detailed information on Medicare spending on prescription drugs, for both Part B (primarily drugs administered in doctors' offices and other hospital outpatient settings) and Part D (primarily drugs patients take themselves) to better inform decision making. The Medicare Drug Spending Dashboard provides important information to the public in an accessible format, but, more important, it served as a first step to provide other information that can enrich the picture.

We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. We continue to look at a number of options in this area.[12]

15. Increasingly, we have been made aware of regulatory and legal barriers that prevent drug manufacturers and health plans from adopting value-based or risk-based contracting concepts. What regulatory options (if any) does HHS/CMS have or is it considering to mitigate government price reporting barriers that impede flexibility for innovative models in drug pricing?

Answer: As part of its effort to provide additional information, increase transparency, and address the affordability of prescription drugs, CMS has released an online dashboard to look at Medicare prescription drugs for both Part B and Part D. These categories include drugs with high spending on a per user basis, high spending for the program overall, and those with high unit cost increases in recent years. Having this information available to the public in an accessible format should inform health care decisions, policy considerations and encourage collective problem solving around these

[12] All responses are accurate as of February 10, 2016

important issues. We believe that, by sharing this information and allowing people to analyze the data, we can increase the knowledge around drug spending and support efforts that are evaluating whether public dollars are being spent most effectively.

Notably, the dashboard does not provide the net prices paid to manufacturers or the rebates to plans and prescription benefit managers. In the Part D program, we are not permitted to disclose the rebates paid by manufacturers to Part D plan sponsors. And for Part B, Medicare does not receive a rebate, but pays 106 percent of the estimated average sales price of each drug, which reflects the average prices paid by physician offices and hospital outpatient departments net of discounts and rebates.

In addition to these efforts related to transparency, we are working to encourage innovation. On September 1, 2015, the Center for Medicare & Medicaid Innovation (CMMI) announced a program to test Value-Based Insurance Design (V-BID) in Medicare Advantage (MA) plans. The program will examine the utility of structuring patient cost-sharing and other health plan design elements to encourage patients to consume high-value clinical services, thereby improving quality and reducing costs. Under this model, organizations can choose to reduce or eliminate cost-sharing for items or services, including covered Part D drugs, they have identified as high-value for a given target population.

On Friday, October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2016 Medicare Physician Fee Schedule (MPFS) Final Rule for public review. Within this rule were provisions finalizing Section 218(b) of the Protecting Access to Medicare Act (PAMA) (PL-113-93) relating to mandating the consultation of appropriate use criteria (AUC) by ordering physicians prior to referring Medicare patients for select advanced diagnostic imaging services. In the final rule, CMS has announced that they will not be able to meet the January 2017 implementation deadline and in fact, stated that they will not commit to any date-certain for implementation of this Congressional policy. Importantly, this policy, which passed the Energy and Commerce Committee, Ways and Means Committee, and the Finance with unanimous support and then the Congress with strong bipartisan support and is viewed as an important "down payment" for payment reforms in Fee for Service (FFS) program.

16. **In light of the fact that CMS has already informed stakeholders that a statutory deadline will not be met, please provide a detailed plan for when CMS intends to fully implement the program and come into compliance with the statute.**

Answer: The Protecting Access to Medicare Act includes rapid timelines for establishing a new Medicare Appropriate Use Criteria (AUC) program for advanced imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite

vast. We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDS mechanism developers. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

17. **Advancements in personalized medicine are becoming even more critical in our pursuit to prevent as well as cure the toughest diseases. Diagnostics are a key component of personalized medicine and are becoming more complex and sophisticated in the information they provide. As a result, the laboratories which perform these personalized diagnostics are increasing in importance. What is the Agency doing to ensure that health plans offered through the Affordable Care Act are ensuring comprehensive laboratory in-network options with ample choices for patients and their providers?**

Answer: As you know, the Affordable Care Act requires all health insurance issuers in the individual and small group markets to offer a core set of benefits called the essential health benefits (EHB). Plans must offer benefits in at least ten broad categories, one of which is laboratory services. The exact laboratory services offered in each state may vary and are based on a benchmark plan, chosen by the state.

18. **When will CMS roll the medical home(s) out, and which medical-home models ultimately will qualify as MACRA APMs?**

Answer: Under the Medicare Access and CHIP Reauthorization Act of 2015, CMS has new authority to develop Alternative Payment Models (APMs) for paying Medicare-participating physicians under Part B, outside of the traditional fee-for-service method. One of these APMs is defined as [3]a medical home expanded under section 1115A[2] of the Social Security Act, which is an exception to the requirement that APMs [3]bear financial risk for monetary losses that are in excess of a nominal amount.[2] Please tell the Committee which models are currently under consideration by CMS to be medical homes expanded under Section 1115A.

MACRA established a particular definition of alternative payment models (APMs) and established what qualifies as an "eligible APM," for purposes of evaluating whether an eligible professional (EP) is qualifying APM participant (QP) for a year. The statute creates a high bar for eligible APMs. Many currently existing APMs – at the Innovation Center and in the private sector – are not likely to meet all these requirements, but some will. We will continuously search for opportunities to expand the range of options for participation in eligible APMs within the contours of the statute, including considering potential medical home models that qualify as eligible APMs. As we move forward with MACRA implementation, we will continue to gather and incorporate feedback from stakeholders as we promote additional physician-focused APMs and work to define the details of the eligible APM criteria contained in statute. We anticipate releasing a

proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

Reform of the Clinical Laboratory Fee Schedule (CLFS), as required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), is of significant interest to me and my constituents. A primary concern is the plan by CMS to use taxpayer identification number, or TIN, to determine which laboratories will report private payer data.

19. **Will CMS ensure all laboratories are able to comply with a new reporting system? How so?**
20. **Will CMS establish an alternative, more expansive methodology to identify laboratories that must report to the Agency, in order to ensure full market representation that includes a statistically significant number of independent, hospital, and physician laboratories?**
21. **If CMS used NPI number or CLIA number to identify laboratories that must report, how many laboratories would be reporting into the new system?**

Additionally, the PAMA statute required CMS to issue final rulemaking on CLFS reform by June 30, 2015, providing both laboratories and the agency with sufficient time to create the necessary systems to collect, certify, report, and calculate data, with new reimbursement rates going into effect January 1, 2017. CMS has failed to meet this schedule. A proposed rule was not issued until October 1, 2015, and there still is no final rule. A January 1, 2017 effective date seems unlikely.

22. **What is the status of the final rule and what are CMS[1] plans to provide laboratories with sufficient time and guidance to comply with reporting requirements?**

Answer: On October 1, 2015, CMS published a proposed rule to implement section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare payment rates. In the proposed rule, CMS proposed to define the term "laboratory" according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. CMS also addressed how to meet the statutory requirement that an "applicable laboratory" receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, CMS proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

CMS is currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an "applicable laboratory". We will carefully consider those comments in developing a final rule implementing PAMA section 216.

Secretary Burwell, as you well know, Obamacare's CO-OP program has been a disaster. After using the American taxpayer as a piggybank, more than half of these entities have failed. I know many of my colleagues share my concerns, and I want to highlight a recent incident with a CO-OP in Ohio, InHealth. Press reports have indicated that InHealth is under enhanced oversight, which means CMS is concerned about its financial stability and is closely monitoring its operations. About 9,000 Ohioans are enrolled in InHealth, and they recently got some surprising news: at the last minute, InHealth decided to drop most OhioHealth hospitals and doctors from their provider network leaving them with few options now that open enrollment has passed. Now, I understand that this Obamacare CO-OP is struggling‹ that'ſs what happens when Washington thinks it knows best and engages in crony capitalism. And I understand that they are just one of many issuers forced to narrow provider networks because of Obamacare's mandates and regulations.

But what I don't understand is how an Administration that crows about consumer and patient protections in the President's health care law can allow a CO-OP it is so closely monitoring to pull the wool over people's eyes and not announce major changes to provider networks until after the open enrollment period has passed.

23. Secretary Burwell, is monitoring decisions about providers networks part of CMS's enhanced oversight of the CO-OPs? Will there be recourse for enrollees who feel tricked?

I am disappointed that CMS has already announced they will not provide a Special Enrollment Period for these Ohioans, a decision that seems all the more perplexing when CMS is allowing one for those who broke the rules and failed to file their taxes. And, frankly, more Washington mandates are not what's needed.

Answer: We are focused on monitoring and supporting the remaining CO-OPs and making sure that consumers whose CO-OPs will not offer coverage for 2016 retain access to high-quality, affordable health insurance.

There are inherent risks in any start up; the insurance market is especially challenging. Each CO-OP is different and faces its own unique challenges. CO-OPs entered the health insurance market with a number of challenges, including: building a provider network and no previous claims experience on which to base pricing, while facing competition from larger, experienced issuers.

Provider networks are established via private contracts between health care providers and insurers, including CO-OPs, who frequently negotiate about the terms of such agreements, and frequently change from year to year. We continue to monitor network adequacy to determine whether networks meet requirements, and will work with state departments of insurance to resolve consumer complaints.

While I understand the disruption a decision like this can cause for consumers, it is important to note that plans still must maintain adequate networks that meet federal and state standards. If consumers are concerned that their plans aren't meeting these standards, they should contact their state Department of Insurance, which has primary authority for overseeing network adequacy.

Part B CMMI Demo:

24. Does data exist to demonstrate that cuts to drug reimbursement for physician administered treatments results in lower health care costs?

25. Has CMS evaluated how this model will impact an oncology practice's ability to remain independent and keep cancer patients out of more costly care settings?

26. Has CMS evaluated how the Part B demo will impact OCM participants?

27. How will CMS select which value based purchasing tools are used for Stage 2? Does CMS plan to go through a rulemaking process for Stage 2 of the demo?

28. Why did CMS choose to include 75% of physicians as opposed to a pilot rolled out to a smaller-scale audience?

29. Once CMS accounts for sequester and the prompt pay discount, how does that affect the calculation of the add-on percentage?

Answer: We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. We continue to look at a number of options in this area.

Last fall, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from state and federal government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation while protecting access and affordability. We came away with feedback to address these challenges in a holistic fashion addressing three important areas: (1) increasing access to information to support better health care decisions, (2) driving innovation that improve and save lives, (3) and strengthening incentives in the delivery system to reward quality care to patients and encourage value-based and outcomes-based decision making.

Coming out of that forum, we have identified several areas of potential opportunity for consideration and collaborative policy development. The need for better information about drug prices and impacts on patients and providers in making better health care decisions was one theme that we heard across multiple panels. To that end, in December, we took a first step forward by providing more detailed information on Medicare spending on prescription drugs, for both Part B (primarily drugs administered in doctors'

offices and other hospital outpatient settings) and Part D (primarily drugs patients take themselves) to better inform decision making. The Medicare Drug Spending Dashboard provides important information to the public in an accessible format, and also serves as a first step to provide other information that can enrich the picture[13].

[13] All responses are accurate as of February 10, 2016.